About the User's Manual

The User's Manual serves for operating this instrument only. Our company shall not be responsible for any consequences and liabilities caused by using this user's manual for other purposes.

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Based on the need of product technical improvement or the file updates, we reserve the right to modify the contents contained in this manual; if the changes do not involve safety issues, the contents are subject to amend without notification

Due to technical upgrade or special requirements from users and with the precondition that the performance of the instrument will not be lowered, some components may vary from the description of configuration in the User's Manual.

The explain for tagging in this manual

⚠ **Warning :** You should know the information for how to avoid the patients edical staff may suffer injury.

Note: You should know the information for how to avoid possible damage to equipment.

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Chapter 1 Cautions in General Operation

★ **The device is for the exclusive use of licensed physicians or personnel.**

★ **Please read the following precautions thoroughly prior to using this instrument.**

★ **Applicability: It is applicable to perform the routine record and diagnosis via electrocardiogram.**

⚠ **Warning: The following measures should be taken when installing or storing the instrument:**

- Keep the instrument away from splashing water, and do not use or install it where air pressure, humidity, temperature, ventilation, air containing dust, sulfur, salt, alkaline gas and chemicals might affect it .
- Install the instrument on a stable plane, and prevent it from vibration and mechanical shock when moving it.
- Install it in a room with complete infrastructure.
- There should be no high capacity machine such as high voltage cable , X-ray &ultrasound device as well as diathermy machine around this electrocardiograph.

⚠ **Warning:**

- The power supply should be capable of providing the proper voltage and frequency as required in the instruction manual as well as sufficient capability.
- Do not install the instrument in a chemical storage area or where gas is generated.

⚠ **Warning: Prior to operation:**

- Check that the instrument is in a complete and normal condition
- Check that the instrument is properly installed.
- Check that all cables are connected correctly and the instrument is grounded correctly.
- It should be given particular attentions when using this instrument with other devices to avoid misdiagnosis or other problems.
- All circuits that contact the patients directly should be examined closely.
- When battery used, please check the voltage and condition of battery first, charge and discharge the battery, and keep the battery fully charged.
- Please tear the protective film before using the instrument.

⚠ **Warning: In operation**

- The physician should observe the patients closely without leaving during the operation. Turn off the power supply and remove the electrodes when necessary to ensure the safety of patients.
- Prevent the patients from contacting the other parts of the instrument and other conductors except the electrodes.

⚠ **Warning: After operation:**

- Turn all functional status back to the initial status , then turn off the power supply.
- Remove the electrodes gently and do not pull the lead cable emphatically when removing the electrodes.
- Clear up the instrument and all accessories for the trouble-free operation for the next use.

⚠ **Warning:**

The maintenance and servings of this instrument should be performed by the experienced technicians. When there is any functional abnormality with this instrument, it should be clearly identified to prevent the instrument from running with fault.

⚠ **Warning:**

Do not make any modification to this instrument.

⚠ **Warning:**

Maintenance and servicing

- The instrument should be subject to the maintenance and servicing regularly (Once half a year at least)
- Since the electrocardiograph is a measurement instrument, the users should have it verified by the legal unit of measurement according to the Verification Regulation of Digital

Electrocardiograph, and the verification cycle should not be longer than 1 year.

- The signal input/output ports (when needed to use) are only permitted to be connected with devices of Class I which is in compliance with the standard IEC60601-1, and the total leak current should be measured by the users to determine if it conforms with the requirement and can be used after connection.
- The electrical basic circuit and the list of parts are exclusively provided to the qualified maintenance stations and personnel confirmed by our company.

⚠ **Warning:**

Products treated after scrapped: the relevant packaging materials, depleted batteries and scrapped products are treated, please remember to follow local laws, The user dispose properly of the scrapped products and materials on the basis of the requirements of local laws, and to support them recovery separation work.

The use of rechargeable lithium batteries:

⚠ **Warning:**

Improper operation may cause the battery becomes hot, fire, explosion, destruction or attenuation of the battery capacity. The use of Rechargeable lithium-ion battery (hereinafter referred to as "Battery"), please read these instructions carefully and use precautions.

⚠ **Warning**:

Polarity of the batteries can not be reversed, or could cause an explosion.

⚠ **Warning**:

Do not fire near the source or the environmental temperature exceeds 60 ℃ battery, do not heat the battery or thrown it into the fire.
Taken to avoid the battery by water splashes, do not drop the battery into the water.

⚠ **Warning**:

Don’t chisel into the battery with metal chisel, hammering, or drop the battery or use the other ways to damage the battery, otherwise it will create fat cells Heat, smoke, deformation or combustion hazard.

⚠ **Warning**:
When you find the battery leakage or emit unpleasant odors, please go away immediately. If the fluid leak into the skin or clothes on, immediately wash with water. If the electrolyte leakage and enter the eyes, do not rub the eyes, immediately with a clean water and see a doctor.

⚠ **Warning**:
Only authorized installation or maintenance engineer can open the battery compartment, replace the battery; and must use the same type of rechargeable lithium batteries which our company's division to provide.

⚠ **Warning:**
When the battery lifetime to reach, or find the battery, smell, deformation, discoloration or distortion, you should stop using the battery, And used batteries according to local regulations for processing.

⚠ **Warning:**
You must turn off lithium battery before plugging; otherwise it will appear black and white, hang and so on.

Note:

- **Taken to avoid the equipment being splashed with water.**
- **During the half-way operation of touch the screen, if the users re-change the touch screen display resolution or display mode, or adjust the touch screen controller, the refresh frequency, felt the cursor with the touch point can not correspond to the time, you must re-touch screen system calibration operation.**
- **The touch screen can not have watered and sticky surface, or other properties of soft material, or likely to cause surface acoustic wave touch screen display are not allowed**

Note:

In this manual, the subsequent amendments (not including the corrections) or revised editions of the dated reference documents are not applicable to this manual, and the latest versions of the reference documents not dated apply to this manual.

Warranty:

For product warranty issues please refer to that "warranty cards" were provides the content in accompanying document, if you have any questions, please call our customer service consulting, customer service hotline: 800-830-6643.

Maintenance Warranty

The manufacturer claims that all parts and materials as well technology of our products, except for the accompanying standard accessories for 6 months, the main unit are fully guaranteed for 18 months dating from shipment. This warranty does not apply to the products modified, disassembled, innovated, and repaired without our authorization or instructions from our company, and the products damaged due to accident, fire, thunder and lightning, flood, intentional destruction, improper installation or operation.

★ **Matters need attention on electromagnetic compatibility (EMC)**

This instrument conforms with the IEC60601-1-2, a safety standard for medical electronic devices or systems. However, the electromagnetic environment exceeding the limit or level defined by the standard IEC60601-1-2 will introduce the unwanted interference to the instrument, disable its intended functions or compromise its intended performance. Thus, if there is any discrepancy with this instrument compared to its intended functions during operation, please do not use it for longer until the adverse affect is identified and eliminated. The appropriate preventing measures are given bellow by this manual for such cases:

■ **Affect from radiated electromagnetic wave**

The use of mobile phone may affect this instrument. Do instruct all the people around to turn off their mobile phone or mini-radio devices when any medical electronic device is installed.

■ **Affect from shock and conductible electromagnetic wave**

The high frequency noise produced by other devices can be introduced into this instrument through the alternating current socket. Please identify the noise source first, and if possible, stop the working of related devices. If they are not allowed to be stopped, measures such as application of noise abatement device should be taken to minimize the influence.

■ **Affect from static electricity**

The static electricity in a dry environment (indoor) may affect this instrument, especially in

winter. Humidifying eh indoor air or pre-discharge the static electricity on the cable and the electrocardiogram recording personnel prior to using this instrument.

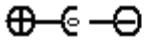
■ **Affect from thunder and lightning**

If there is thunder and lightning occurring around this instrument, a voltage shock may be caused in this instrument. If it is considered as dangerous, you can pull off the plug of power supply from the alternating current socket to run this instrument by its internal power supply.

★ **Instrument classification**

1) By type of shock proof: Class Ⅱ, internal power supply
2) By degree of shock proof: Type CF device
3) By degree of unwanted liquid proof: Ordinary device (closed device without liquid proof)
4) By safety degree when using in the presence of inflammable anesthetics mixed with air, oxygen or N2O: This instrument should not be used in the presence of inflammable anesthetics mixed with air, oxygen or N2O
5) By running mode: Continuously running instrument

★ **Interpretation for symbols related to this instrument**


DC work mode

on/off

Equipotential terminal

USB Port

LAN Port

SD SD Port

ENTER

Attention (consult operating instructions for details)

Typy IEC, CF equitment

Typy IEC, CF equitment with protector against defibrillation

Note:

Refer to the menu of status setting for Information items and interpretations on the display screen.

This manual is subject to change, customers may not be notified in time. Inconvenience, please forgive!

Chapter 2 Cautions in Operation

★ **To assure proper operation of the unit, please read through this manual, and pay special attention to the following operating precautions.**

Note:

This instrument should be installed on a smooth and stable working bench, and be prevented from the intense vibration and shock when moving it.

Note:

The frequency and voltage of the alternating current should meet the requirement, and the current capacity should be sufficient.

Note:

When the integrity of the protective wire is unsure, please use the internal DC power supply.

Note:

The applied part of circuit works in a floating ground condition, and the design conforms with the safety standard for Type CF, thus it is able to record and display the electrical signal of body surface generated by the activity of cardiac, but can not directly act on cardiac.

Note:

For the accuracy of the electrocardiogram tracing, this instrument should be installed in a quiet and comfortable environment.

Note:

Turn off the instrument immediately if there is any abnormality occurring during the operation.

⚠ **Warning:**

The power supply cable should be 3-core cable when using this instrument with the alternating current, otherwise the hazards of electric shock may be introduced to the patients and operators. When the available 3-core cable is unusable, please use the battery for power supply.

⚠ **Warning:**

The room should be equipped with the complete power supply system and grounding system, otherwise it might be harmful to the patients.

⚠ **Warning:**

When it is used in combination with the cardiac defibrillator, the contact with patient or hospital bed should be avoided. All the electrodes which are connected or unconnected to the patients as well as the patients themselves are not necessary to be grounded .All the electrodes for use should be the Ag-Cl electrodes provided by our company . The patient cable specially provided by our company should also be used for ensuring the protection against the charging of the cardiac defibrillator. It is not recommended to use this instrument in combination with the other electric stimulators. However, if necessary, they should be used in the presence of professionals and under the appropriate directions. When the instrument is used in combination with the cardiac defibrillator or the other electric stimulators (such as HF surgical units), it is recommended to use the disposable chest electrodes in the shape of plate to prevent the adhesive metal electrodes from burning the skin of patient.

⚠ **Warning:**

Be cautious when the patient is connected with more than one instrument, because the total leak current may be harmful to the patient. Only the Class I devices in compliance with the standard of IEC60601-1 are allowed to be connected to this instrument, and the total leak current should be measured by the users to determine that if it meets the requirement and can be used after connection.

⚠ **Warning:**

When the patient is connected with a cardiac peacemaker, the accuracy of ECG testing and the analysis result might be affected. In this case, it is recommended for physicians to perform the identification and analysis in combination with the waveform. However, the potential risk will be increased in this case. Thus it should be given particular attention to the safety problem when recording the ECG in this case, and the appropriate measures should be taken to ensure the leak current at a acceptable level.

⚠ **Warning:**

Keep the high frequency electric knife away from the electrodes to prevent the patients from burning. Make the electric resistance between the high frequency electric knife and patients' body as low as possible, and be cautious particularly. If necessary, the plate electrodes can be used because of its larger contact area to limit the high frequency current density into an acceptable range.

⚠	**Do not use this instrument in presence of inflammable gas such as anaesthetics , oxygen, hydrogen or in presence of inflammable chemicals, otherwise it may cause the explosion or fire disaster.**

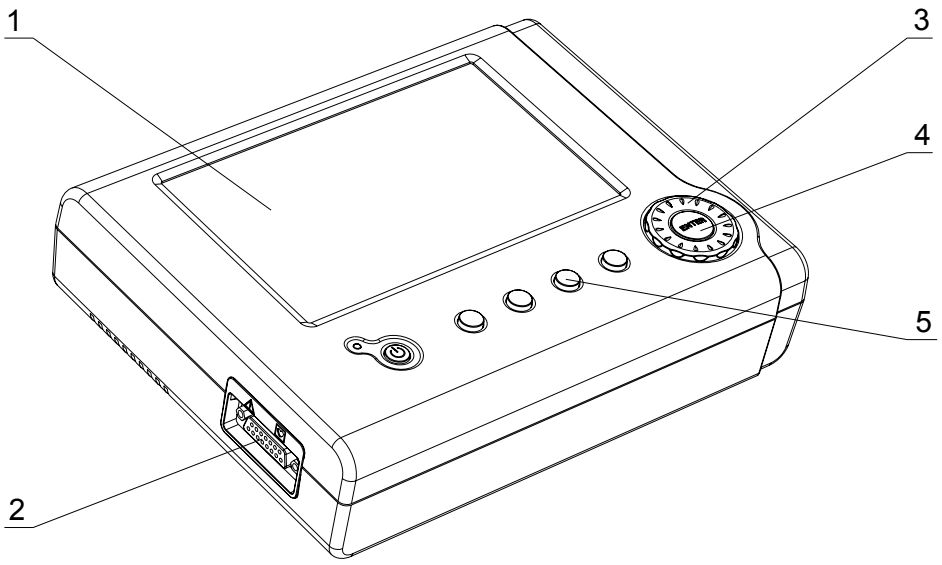
⚠	**Do not use this instrument in the medical hyperbaric chamber, otherwise it may cause the explosion and fire disaster.**

⚠	**Especial intention:The cardiac defibrillazing &monitoring unit not exit in this instrument, you must use our company's lead lines which has the electric defibrillation function.**

Chapter 3 Features and Operating Principles

3.1 Name and function for various parts of the instrument

- **Front view**



1. Color LCD touch screen

For displaying the electrocardiogram, information of the patient tested as well as the instrument status.

2. Lead connector

For connecting the lead lines

3. Shuttle

For moving the optional menu and the functional button.

4. Enter Button

For confirming the current input.

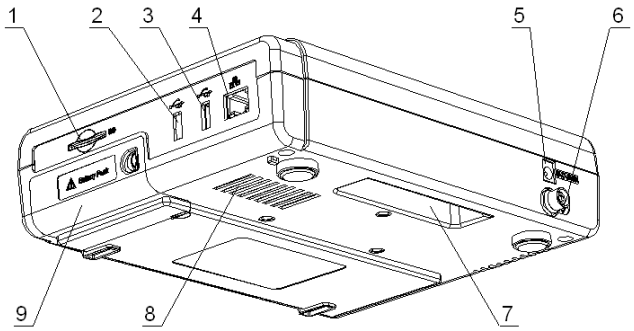
5. Operating buttons

For controlling the operations to this instrument and information input

Note:

- **Do not place the heavy things onto the LCD or strike it, or else the LCD will be damaged.**
- **Do not use too much force on the touch screen, using the touch pen slightly as soon as you can.**
- **Put it away or cover it when this instrument is unused to keep it away from the splashing water.**
- **Do not press the buttons with the sharp or hard articles, or it may cause the permanent damage to the buttons.**

■ **Undersurface and lateral surface**



1. Slot for SD card

For identifying and reading the SD card, to support capacity 2G.

2 and 3. USB port

With the printer (supports USB Interface) connection, for analysis of ECG and direct printing; with USB hard drive connected to the storage of ECG data; connect with the scanner which has USB interface, it can scan the patient ID number.

4. LAN Port

For network connection. LAN to transfer data to ECG editing workstation and management of data transmission and sharing local area network

5. AC Interface

Connect the AC power cord

6. Grounding terminal：

For connect the equipotential grounding wire.

7. Embedded handle：

For moving or carrying this instrument.

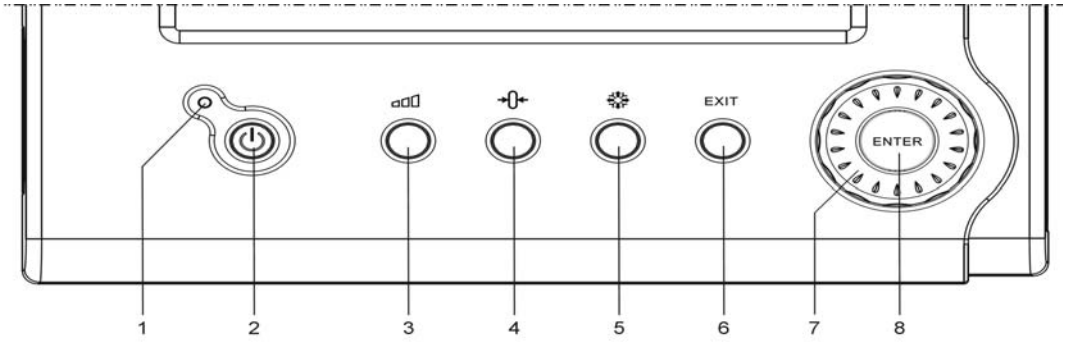
8. Thermal windows

Machine inlet ventilation openings

9. Battery compartment：

For loading the rechargeable lithium battery with high performance, （14.8V/4400mAh）

- **Operating buttons area**



1. Power supply indicator light：

For indicate the current power supply status for this instrument (Plug the power cord blinking green light that is charging, green light without flash to indicate the battery capacity is full.)

2. ON/OFF button：

For turn on or turn off this instrument. If there is a failure with during the operation, you can hold down this button for 3 sec. then release it to shut down this instrument by force.

3. Sensitivity switch/Back button：

For switching the sensitivity manually in the non-setting status. The sensitivity can be divided into 4 levels as 2.5mm/mV、5mm/mV、10mm/mV、20mm/mV.

4. Lead shutting off/Direction button：

For stabilizing the lead input signals instantly and resetting the printing of the lead output signals in the non-setting status.

5. Freeze button

Freeze the current lead waveform display for easy observation and diagnosis.

6. EXIT Button

Press this button to go back to the main menu.

7. Shuttle

For moving the optional menu and the functional button

8. Enter Button

For confirming the current input.

3.2 Principle introduction and block diagram

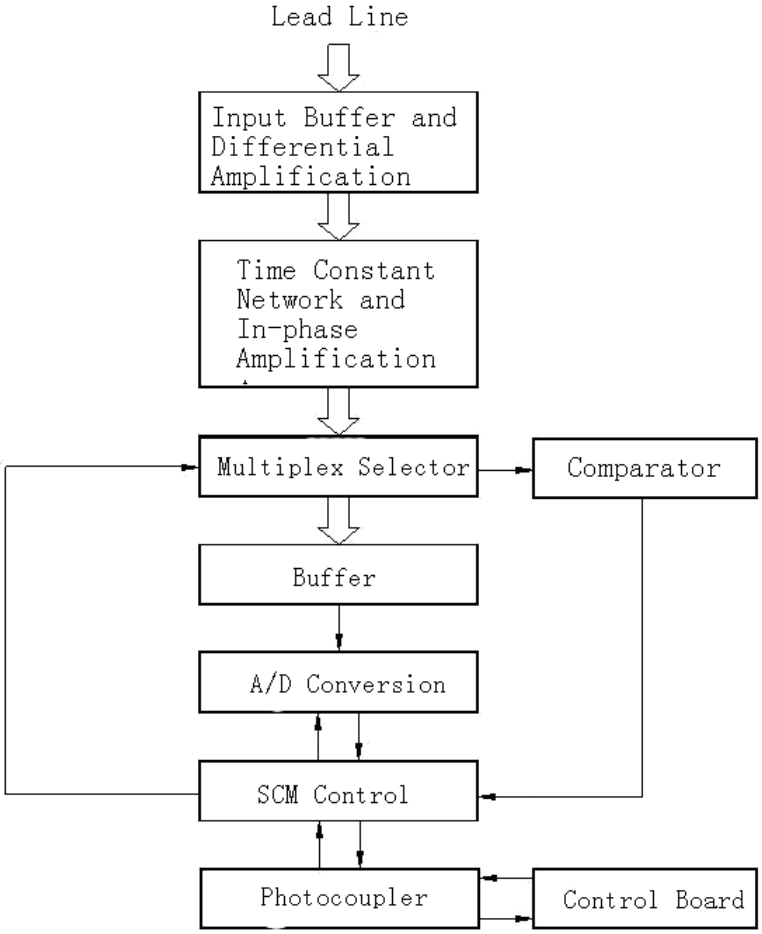
1 Amplification (collection box)

(1) Principle introduction for the amplifying unit

The floating ground circuit of the whole instrument is a signal capture system which consists of analogue circuit and A/D converting system. The analogue circuit is composed of lead signal amplifier, anti-aliasing low-pass filter, channel switch, lead shut-off, lead- fail detector, etc. The CPU system of the whole instrument is responsible to coordinate the various circuits such as A/D converter, channel switch, lead shut-off and lead-failure detector to perform the signal capturing and lead-fail detecting. The control information between the floating ground and ground circuit and A/D converting data is transmitted by the photocoupler.

The sampling rate for lead signal is 1000/960Hz, while the sampling rate for lead-fail signal is 100/120Hz, and the cut-off frequency for anti-aliasing low-pass filter(-3dB) is 200Hz. The sampling rate conforms with the standards of AHA (American) and CSE (European) which require that the sampling rate of electrocardiograph with the analysis function should be no less than 500Hz. The anti-aliasing low-pass filter can limit the input bandwidth of A/D converter while ensuring the wanted signal bandwidth to avoid the signal aliasing caused by the sub-sampling of high frequency signal.

(2) Block diagram for the amplifying unit

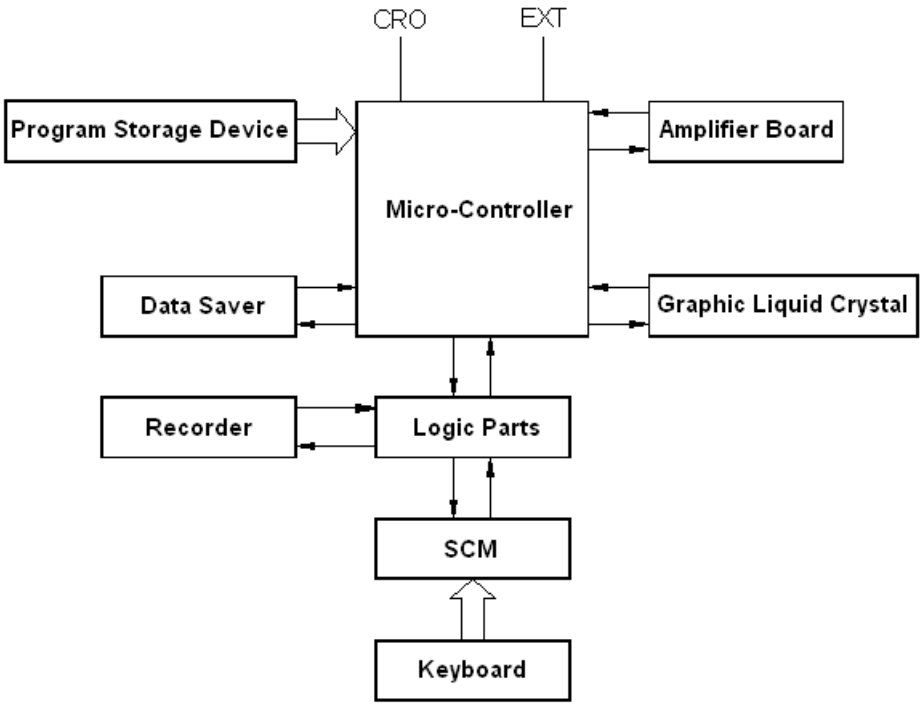


2 Controlling

(1) Principle introduction for the control unit

The control system is composed of printing controller, keyboard controller, liquid crystal controller and CPU system, etc. The lead signal acquired by the signal capture system is transmitted by the high speed photocoupler to the CPU system, then subject to the processes of digital filtering, gain controlling and printing driving, finally transmitted to the printing controller to perform the printing of the waveform. After printing, the waveform will be measured, analyzed and processed by the CPU system. The CPU system can also receive the interrupt signals and the key coding from the keyboard to perform the key interruption processing. In addition, such functions as lead fail detection and paper compartment empty detection, battery voltage control, automatic turning off the power supply, CRO analogue output, sampling and printing for EXT input are all administrated by the CPU system. The keyboard controller produces the keyboard scanning signals to perform the processing of key-jitter elimination, then the key coding and the interrupt signal is received and processed by the CPU system. The liquid crystal controller is responsible to the data and commands from the CPU system to perform the displaying the control status of the whole instrument.

(2) Block diagram of the control unit



Chapter 4 Preparation before Operation

4.1 Location selection

ECG-8080 is not to be limited to be used in hospitals and clinics. Because of the portable feature it can be used anywhere with the battery. It is applicable to outdoor occasions such as group examination.

■ The following aspects should be considered when selecting the location to install this instrument to recording the electrocardiogram accurately.

■ Keep the instrument and the bed for testing away from the high voltage cable. The substantial radiation source around this instrument may introduce the noise interference to this instrument.

■ Keep this instrument away from devices such as X-ray, ultrasound, radio machines and fluorescence light because they are probably the substantial radiation sources.

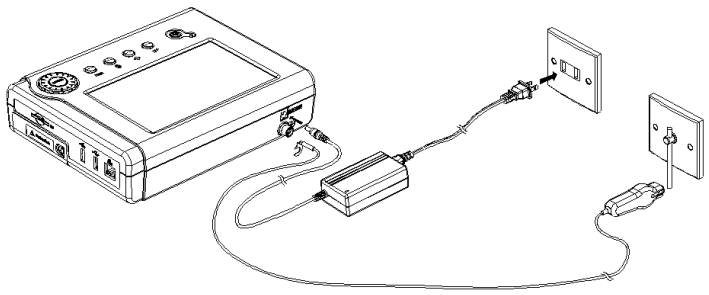
■ Please use this instrument with the ambient temperature of 5℃~40℃.

■ Please use this instrument with the ambient humidity of 25%~95% (without condensation).

4.2 Connection of the power supply

1) Using the AC power supply

ECG machine will be provided with one end of the power cord into the machine's power outlet, the other end into a wall socket, the ground where the environment pillar and ground machines reliable connection (as shown).



When this instrument is used with other medical devices, please use the external grounding cable provided together with this instrument. Connect the grounding terminal of this ECG with the same grounding terminal of the other devices to prevent the patient from the electrical shock. When there is any leak current with the other devices, this connection will induce it into the ground for protection.

2) Using the battery

When the battery is required to be used as a power supply, Users can use the specify high-performance rechargeable lithium battery. Please check the capacity and status of the batter. Charge and recharge it before using the battery..

Note:

The reliability of grounding for this instrument can be enhanced by connecting one end of the accessorial grounding cable onto the grounding column of the instrument while connecting the other end to the ground. Do not use the water pipe or the other pipes as a grounding cable, or else the safety protective measure of first level of this instrument is ineffective, and the patients might be in danger of electrical shock.

Storage battery

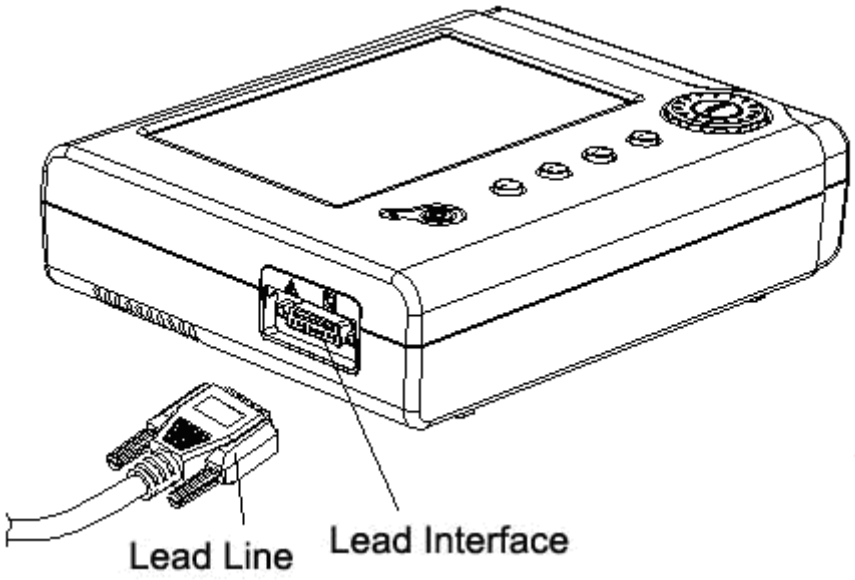
When the battery pack not be used more than 90 days , please store it at temperatures between -20 ~ 30 ℃ dry; when the battery storage for more than a month, due to battery self-discharge, charge before use.

Battery scraps

Before the disposal of waste batteries from your local solid waste management officials for recycling or for proper handling. The battery pack can be recycled, after the end of the battery life, according to the state or local law can not be attributed to this cell treatment of municipal waste is illegal.

4.3 Connection of lead lines

Connect the lead lines of the accessories into the lead port of the instrument and tighten the screw as the following picture.



Note:

- **Do not use the other types of lea lines except the designated special lead lines provided together with this instrument.**
- **The lead port is exclusively for connecting the ECG signal, Not used for other purposes.**

4.4 Select and connect the printer

The instrument can be connected directly through the USB interface to the printer, the recommended printer model are:

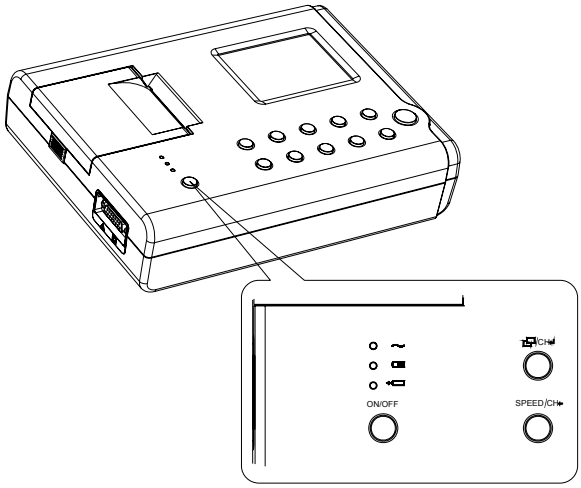
HP 1010

HP P1505n

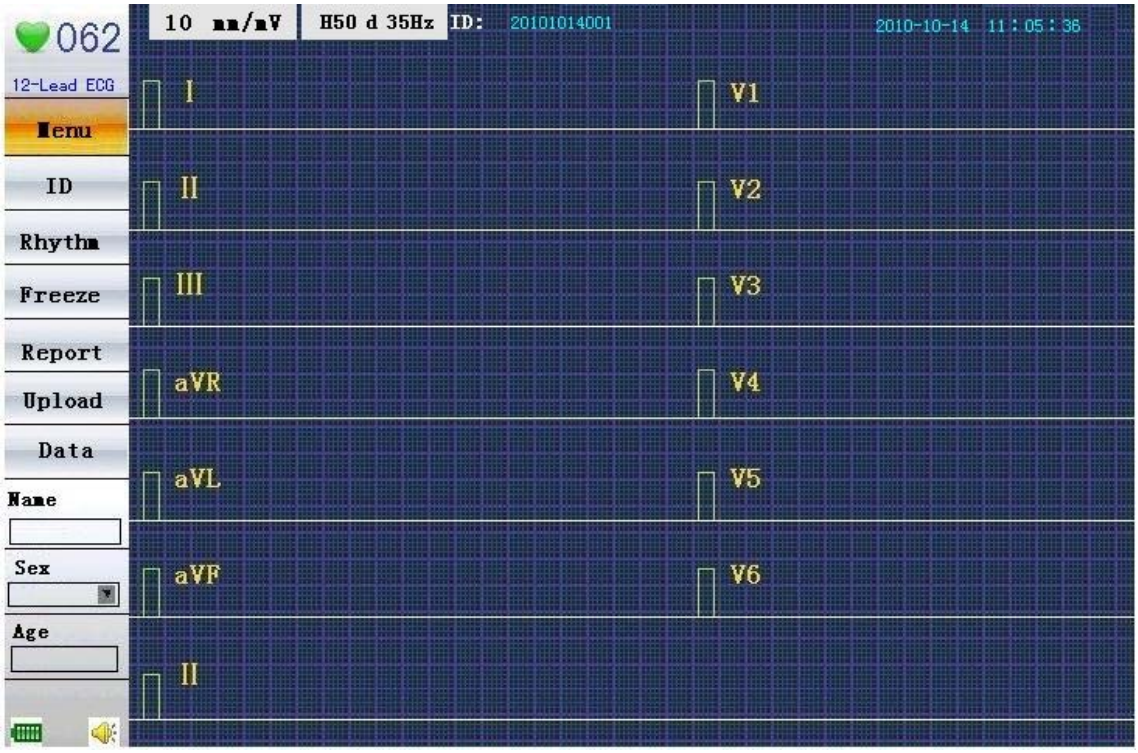
HP P2035

4.5 Start the instrument

As the flowing picture, press the operating button of (ON/OFF), the power supply indicator light will light and the instrument turns to be in initial status,



When the instrument enters into the system and the following initial picture is displayed on the LCD screen, it indicates that this instrument has entered into the stand-by status and you can start operating.

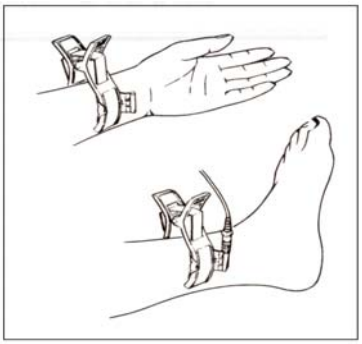


4.6 Connection of electrodes

The connection of electrodes is critical for the accuracy of electrocardiogram recording, thus please make sure the contact condition of the electrodes is good .New and old electrodes, as well as the reusable and the disposable electrodes may not be used simultaneously. If used, the quality of the recorded electrocardiogram may be affected to a large extent. The electrodes and lead plugs are not allowed to contact the other surface or conductor such as the metal bed. If the electrodes replacement is needed, please replace all the electrodes for once.

1) Electrodes connection onto limbs

The eletrodes for limb should be connected onto the soft skin of the limbs. Clean the skin for electrodes connection with the medical alcohol first, then coat it with a little electrodes cream. The electrodes for limbs should be connected as follows(see the following picture):



R (RA) Connected onto the right hand

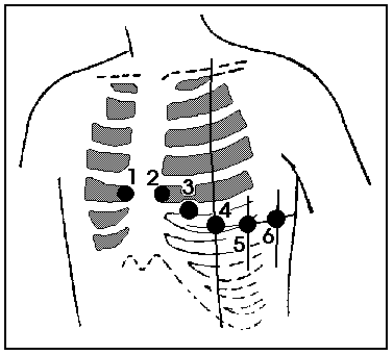
L (LA) Connected onto the left hand

RF (RL) Connected onto the right leg

F (LL) Connected onto the left leg

2) Electrodes connection onto chest

Clean the skin of chest for electrodes connection with the medical alcohol. Coat the electrode cream on these sites in a diameter of about 25mm as well as the edge of adhesive plates of the electrodes. Compares the suction bulb of the chest electrodes to make the chest electrodes adhere to the V1~V6 sites.The chest electrodes should be connected as following picture:



C1 (V1) : 4th intercostal place at the right margin of the sternum.

C2 (V2) : 4th intercostal place at the left margin of the sternum.

C3 (V3) : Midway between C2 and C4.

C4 (V4): 5th intercostal place at the left mid-clavidular line

C5 (V5) : At the horizontal level of C4 , at the left anterior axillary line

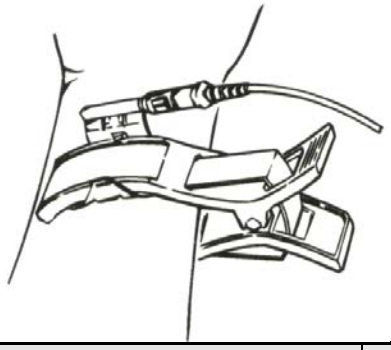
C6 (V6) : At the horizontal level of C4, at the left mid-axillary line

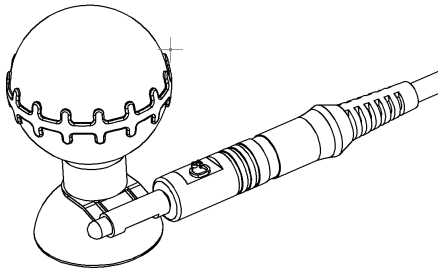
Note:

The electrodes cream should be coated separately, and please prevent the electrodes from contacting each other to avoid the short circuit. If the electrode cream is not available , the ECG test should be performed for a short term as follows: Clean each site for electrodes connection with the 75% alcohol , then connect the electrodes onto them immediately to ensure the electrodes contacting sites with a proper humidity. Do not replace the electrode

gel with the physiological saline or else the electrodes might be corroded.

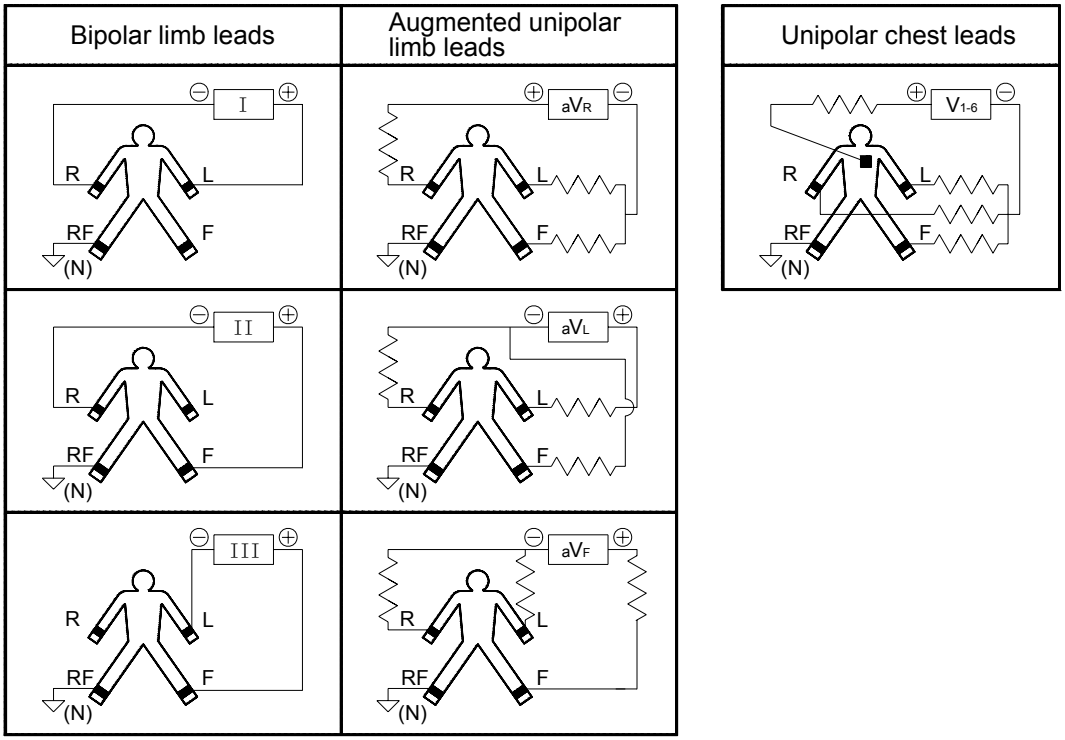
- **Comparision table between the line color and the corresponding electrodes**





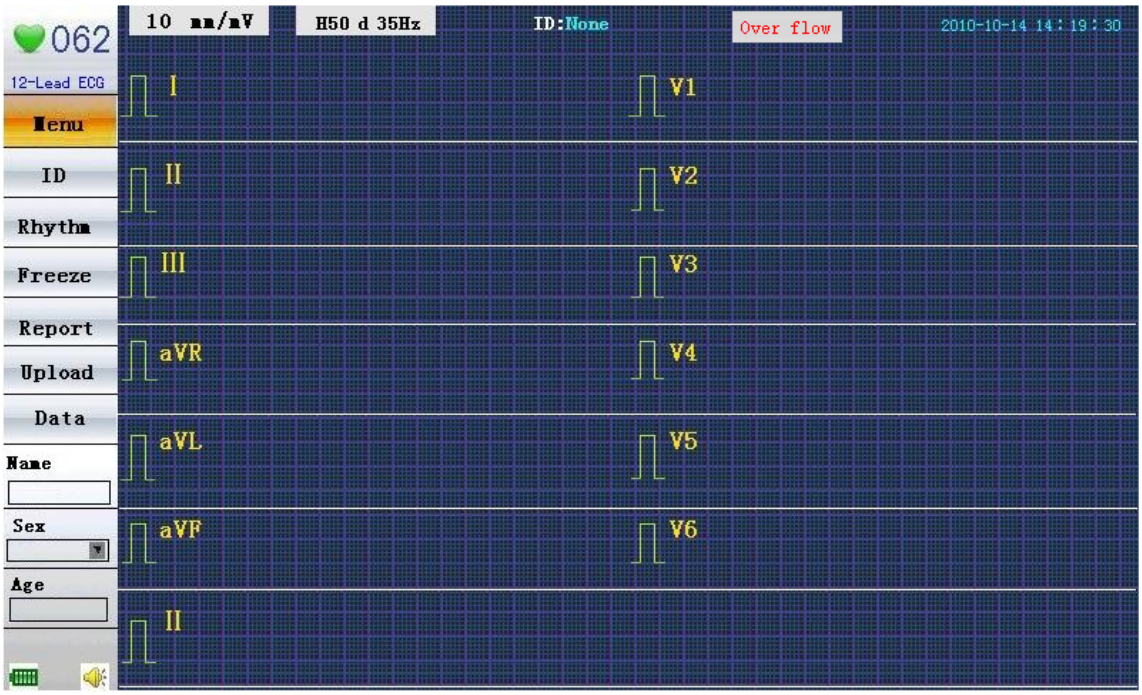
LEAD		European standards		American Standard	
Sites for electrode	**Lead line color**	**Symbol for electrod**	**Color code for electrod**	**Symbol for electrod**	**Color code for electrod**
Right arm	Gray	R	Red	RA	White
Left arm	Gray	L	Yellow	LA	Black
Right leg	Gray	N or RF	Black	RL	Green
Left Leg	Gray	F	Green	LL	Red
Chest 1	White	C1	Red	V1	Red
Chest 2	White	C2	Yellow	V2	Yellow
Chest 3	White	C3	Green	V3	Green
Chest 4	White	C4	Brown	V4	Blue
Chest 5	White	C5	Black	V5	Orange
Chest 6	White	C6	purple	V6	purple

- **Lead modes and system diagram**


Bipolar limb leads
Augmented unipolar limb leads
Unipolar chest leads
I
aVR
V1-6
II
aVL
III
aVF
R
L
RF
F
(N)

4.7 Indication for channel overflow

The saturation of amplifying unit will occur when the amplitude of input is over the range of the instrument. The instrument will display indication for overflow as the following picture. This phenomenon often occurs in the following two situations: one is the time connecting the lead lines to the patient, the other is the time that the body of patient moves when operating.

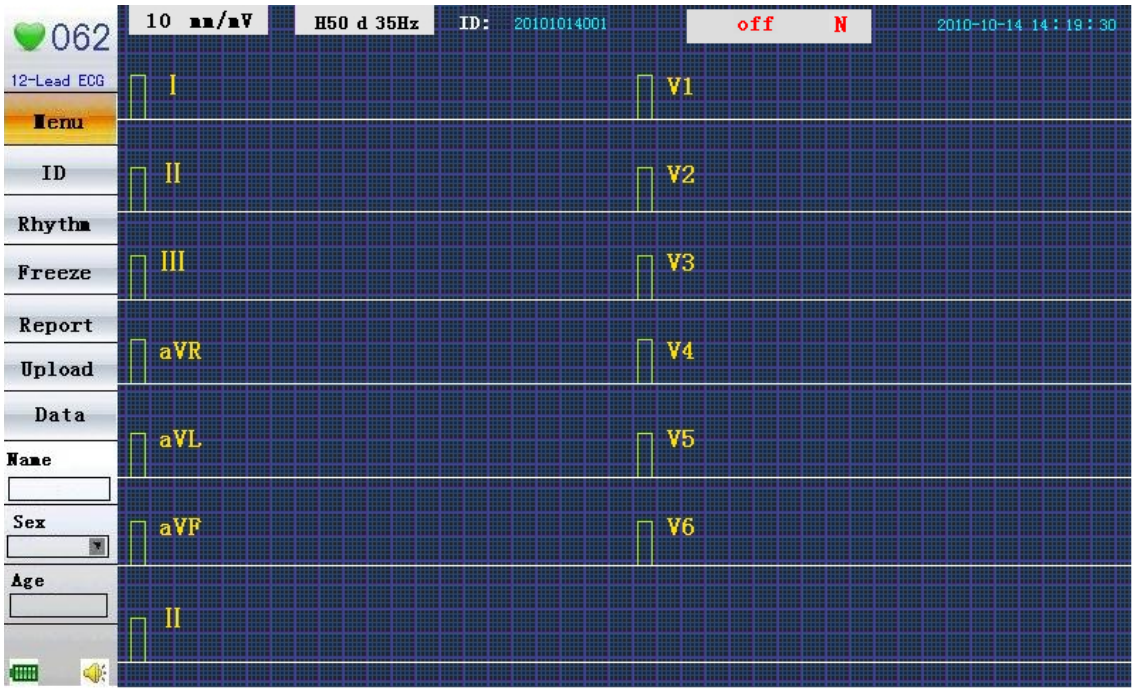


You can press the Lead Shut-Off Button (if necessary, press it many times) to handle the overflow. After the waveform of each channel instantly stabilizing, you can operate it for other use.

4.8 Indication for lead fail

This instrument can detect the lead connecting status continuously, and if any lead fail is detected, the corresponding lead code will be displayed on the top right corner of the LCD. The

following picture will be displayed on the LCD:



If any lead fail is detected , the corresponding leading waveform will not be displayed . The users should reconnect the electrodes or the electroes leading based on the given information about the electroes or electrodes leading detachment.

Note:

1. [DISCONNECTED:*]:

① When the lead line with the patients or host is not reliable connectivity, ECG can not correctly send, that "*" of the symbols is displayed to warn , "*" indicates the current lead; ② when polarization voltage is over specified value of equipment , the symbols is displayed to warn.

2. In the course of use, "DISCONNECTED:*" of the symbols is displayed to warn the screen, to dealt with according to the following approach:

① Press "lead shutting off " button to intervene manually, to eliminate the effects of strength exceeds the value of the polarization voltage on the amplifier products, will enable amplifiers rapid return to normalcy; ② Press "lead shutting off " button to intervene manually, still can not lift a state of alert, they should double-check the connection of the corresponding electrode and the skin of patient , the electrodes and l the lead lines or host of is reliable, when such a reliable connection, the state of alert lifted .

Chapter 5 Operation Procedures

5.1 Inspection before Operation

- Is there any electrical equipment which may introduce the radio-frequency or the power

supply interference such as X-ray, ultrashort wave device around this instrument? If there is, they may introduce the interference to the ECG instrument. If necessary, please turn off this equipment or perform the test in another location without interference.

- Is the ambient temperature and humidity in compliance with the requirements for using this instrument?
- Is the connection of power supply cable good? Or is it nter twisted with other cables?
- Is the connection of lead lines good? Or are the lead lines close to the AC power supply cable?
- Is the connection between the lead line pins and appropriate electrodes correct?
- Is the connection of electrodes good?
- Is the electrode contacting skin of the tested patient subject to the appropriate pretreatment?
- Have the electrodes been contaminated? If they have, please remove the stains with the alcohol and the soapsuds.
- Is the connection of electrodes too loose? If it is, please tighten them.
- Are the new and old electrodes used together?
- Is there any contact between different electrodes (particularly in the chest area)
- Is the tested patient too nervous? If he (she) is, please explain to the patient that the ECG test is a simple process without any harm to the patient to relax him (her).
- Is the tested patient acting or speaking?
- Is the bed too narrow for the patient?
- Do the naked parts of the patient body such as hand an foot contact the metal part of the bed? If they do, the AC interference may be introduced to the electrocardiogram tracing.

- Is the examination room comfortable?

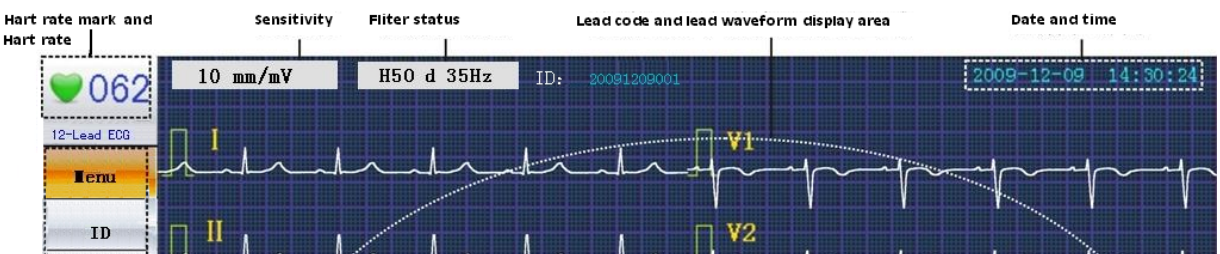
- Is the quantity of the recording paper sufficient?

Note:

For the safety of the examined patient and stability of the electrocardiogram recording, the above inspection should be finished before operation. Make sure all the conditions about the instrument and patient normal before electrocardiogram recording.

5.2 Electrocardiogram recording screen

Start the instrument and make sure all the lead connection is correct, while the electrocardiogram can be recorded. The following electrocardiogram recording screen will be displayed on the LCD.

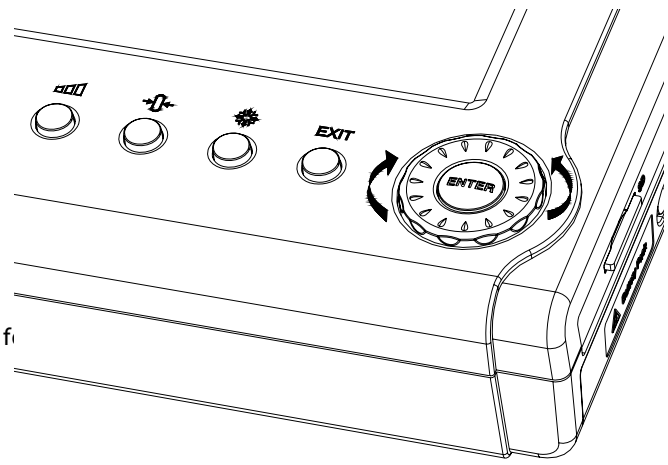


Users can touch sensitivity; filter status code leads to change its settings. Select the Exit option, or press the panel by “EXIT” button to exit.

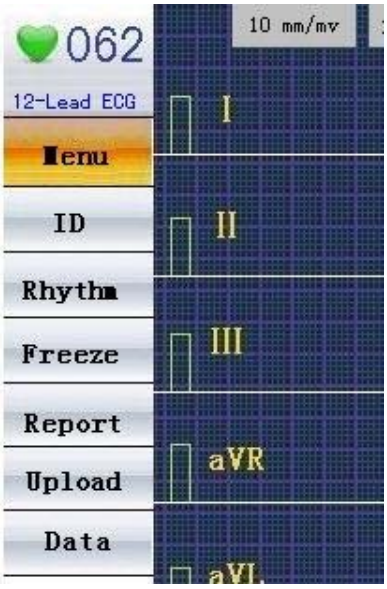
5.3 Basic Operation

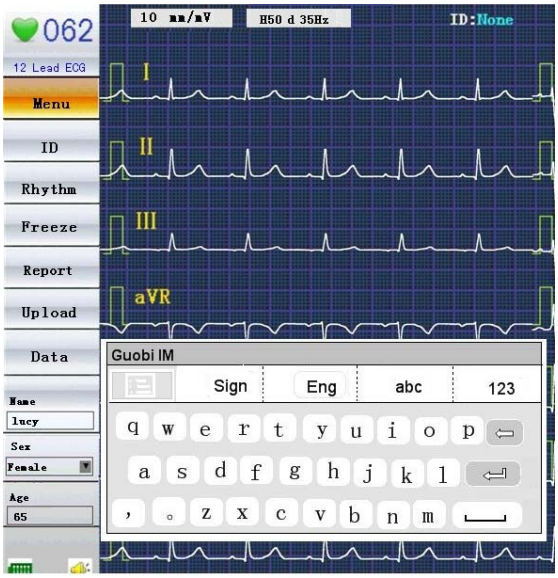
User can operate the ECG instrument by a touch pen or use the shuttle knob, when turn the shuttle and the liquid crystal display the cursor in the “menu option” back and forth move or use the touch pen directly, the selected “option will be displayed as orange, press the” Enter” button to enter into the next level menu, the related operation and interface as following below::

Shuttle and buttons



Operation menu option



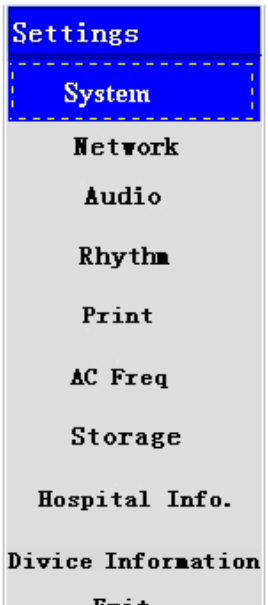


In the main interface, you can turn the shuttle to touch pen, or the name, gender, age options, see the pop-up a software disc, enter the patient's name, sex, age, detailed operation method refer to Chapter 7 of the patient information input: parameter setting method : ID number, medical record number, name

From the main menu interface into the next level, the various interfaces as shown below,

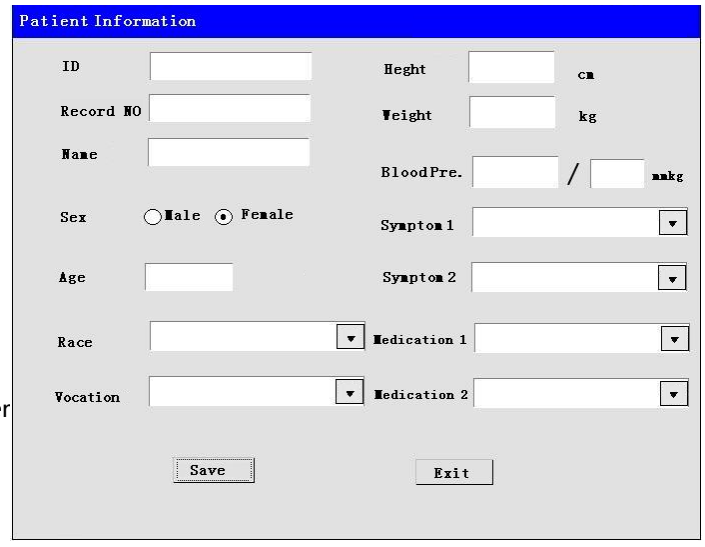
"Menu" interface

Set of system parameters
and data management operations



"ID" interface

Input patient information



Oper

“Rhythm” interface

R-R interval time measurement

“Freeze” interface

Freeze and Browse the currently displayed，ECG waveform (Can freeze the current time of 60 seconds ahead of data

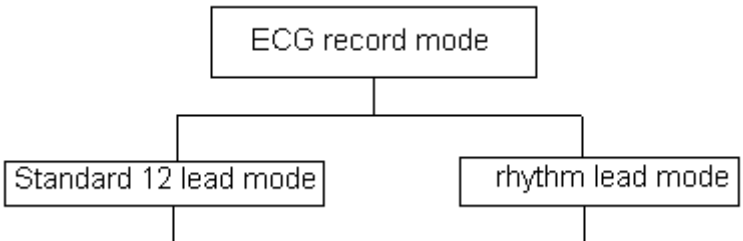
“Report” interface

Automatic Analysis of the ECG

“Upload” interface

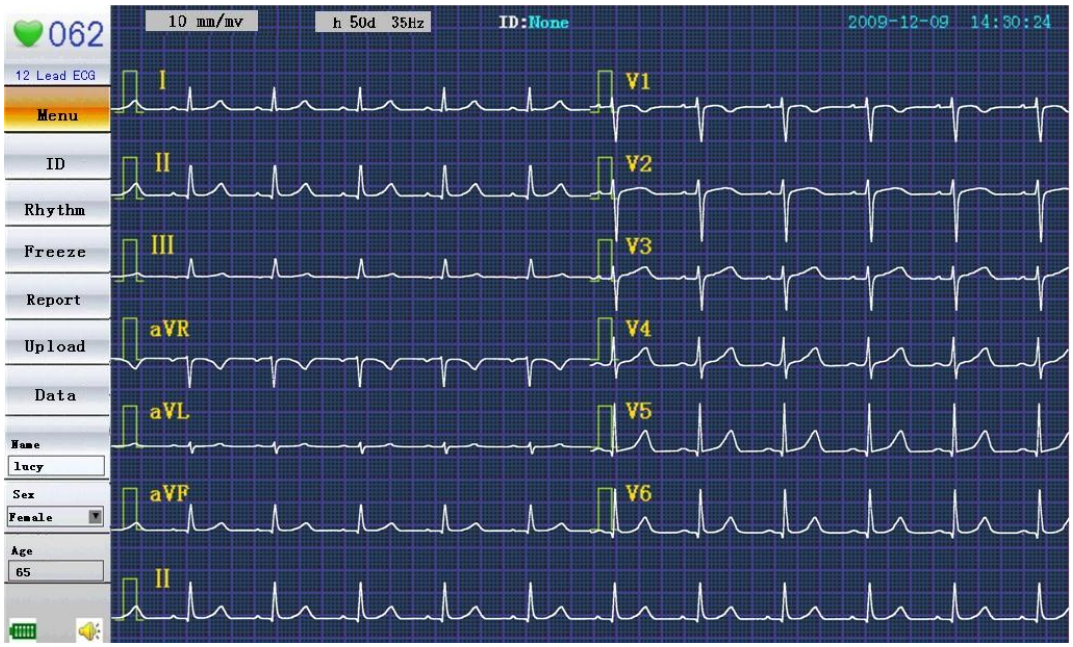
5.4 Electrocardiogram recording operation

The instrument provides standard 12-lead and rhythm lead mode, two modes can be made to collect an automatic analysis of ECG, and gives a detailed analysis report, the next graph shows measurements model structure.



1) standard 12-lead mode

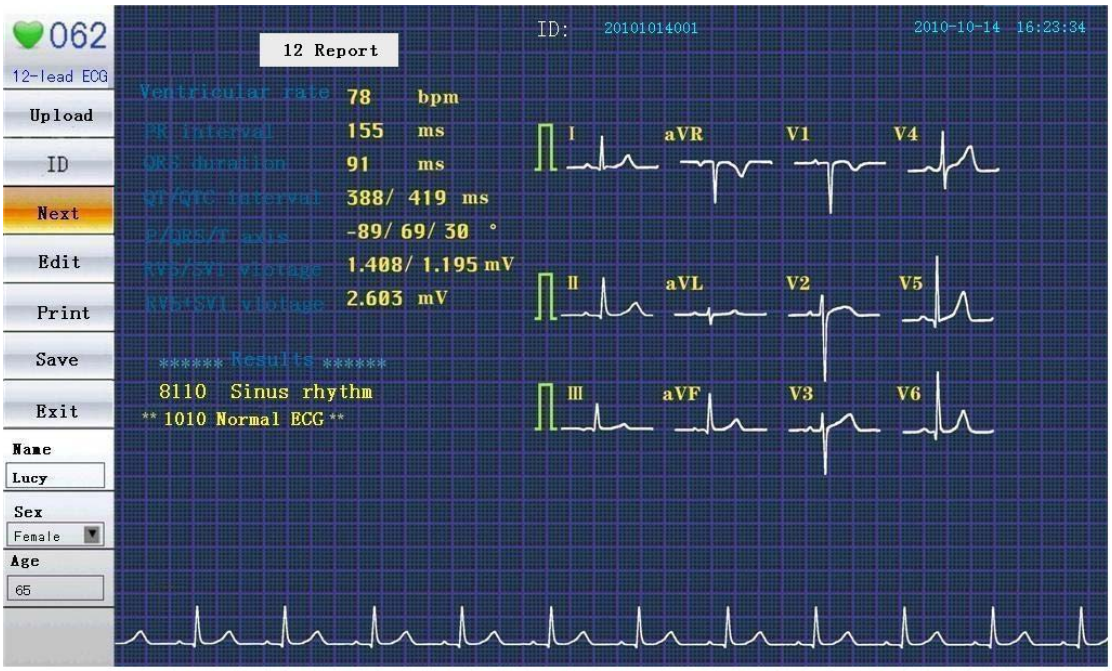
The machine factory default measurement mode to “standard 12 lead” mode, the LCD display shows the machine working status;, as the following picture:



a. The users can examine that if the ECG waveform of leading is stable through the displaying of the heart rate. If necessary, you can stabilize the leading waveform instantly by pressing the “Lead Shut-Off Button”.

b. Press the “sensitivity switch” button or use a touch pen at the top of the screen to set the sensitivity. There are fourth levels:2.5mm/Mv、5mm/Mv、10mm/Mv and 20mm/Mv；

c. Turn the shuttle knob, select “Report” option in the operation of the menu bar, press the “Enter” button, or use the touch pen directly on the screen. It will automatic analysis ECG waveforms and displays a detailed analysis report. As the following picture:

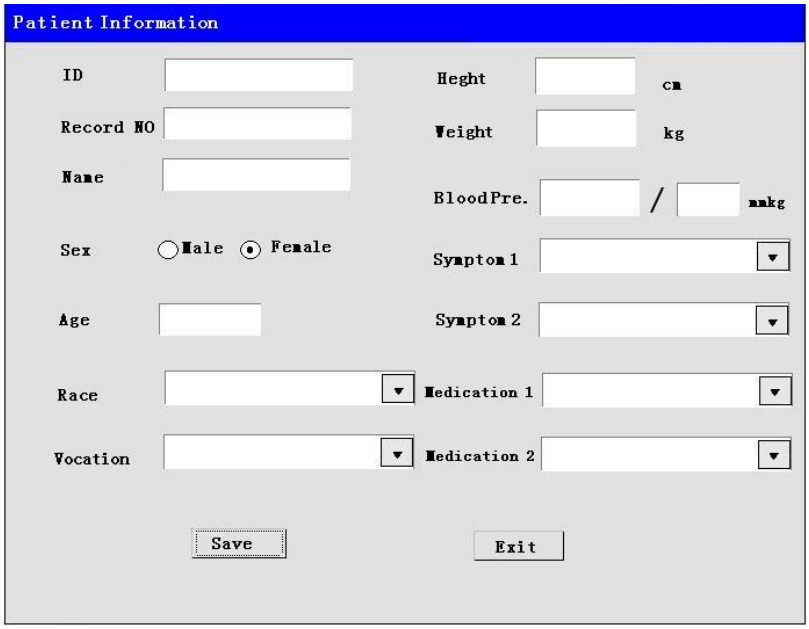


In the “report” interface, you can select the “upload”, “ID”, “Next,” “Edit,” “print” “save” or “exit” and other operations.

Move the cursor to the “Upload” and Click “Enter” button or use the touch pen directly, the

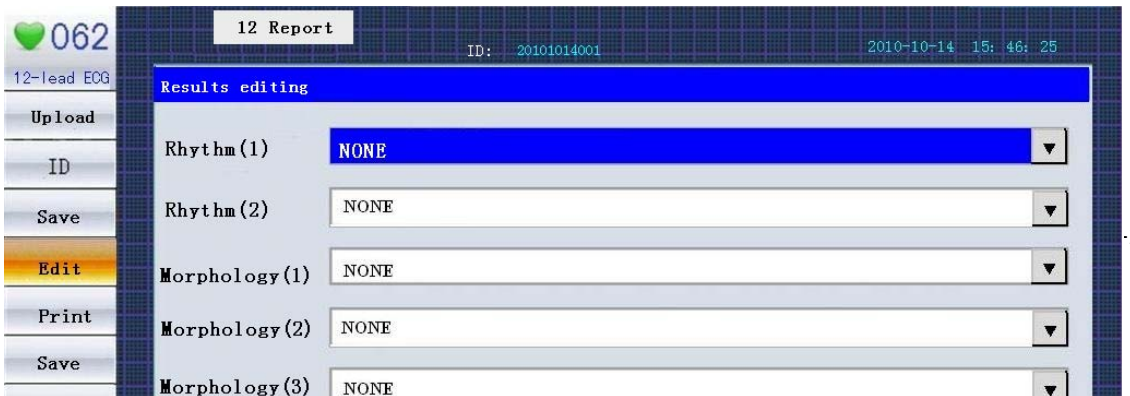
copies of ECG data can be uploaded to the ECG management software, to ensure the accuracy of the data can be uploaded, please check the “Network” Setting, whether the local IP and network server address in the same sub-network segment, even whether the network server address in the instrument same to the IP address in the receiving computer.; and please connect the network correctly.

Move the cursor to the “ID” and click “Enter” button or use the touch pen directly to enter the “patient information” interface, as shown below: (detailed operation see Chapter 7)



Click “Save” to save the patient information, and click “Exit” to patient exit.

Move the cursor or use the touch pen to the “Edit”, and Click “Enter” button to enter “Results Edit” interface, you can make changes to the current results, as shown below:



If the printer is connected well, you can use the touch pen or use the shuttle to move the cursor to “Print”, then click “Enter” button to print the report.

Turn the Shuttle or use touch pen to move the cursor to the “Next”, and then Click “Enter” button, it will be displayed a copy of the data as follows:

Use the touch pen or turn the shuttle to move the cursor to “Save” and press the “Enter” button. In the system menu, users can select storage according to the actual situation; the instrument will automatically save this report data to the specified storage. Use the touch pen or turn the shuttle to move the cursor to the top of the screen as 12 Report (Print mode settings), this instrument supports for three kinds of printing modes: 12-channel print, 3 +1

channel print, heart print. Use the touch pen directly or turn the shuttle to move the cursor to “exit” and press the “Enter” button to exit to the main interface.

Note:

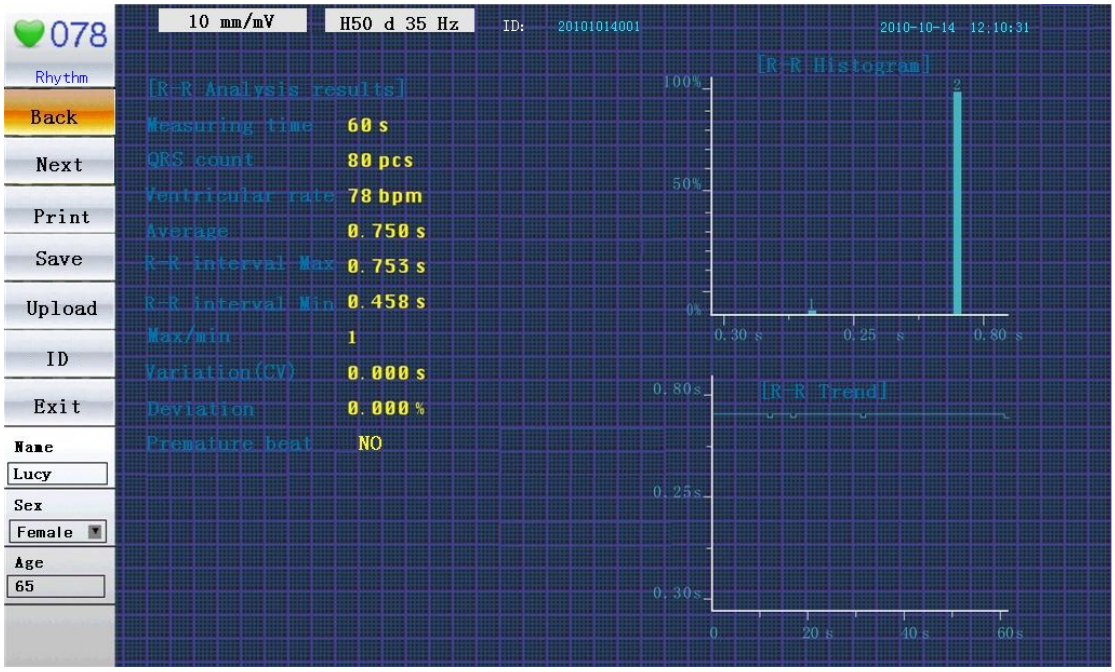
The automatic analysis function is provided by this instrument, however, this function is just to perform the ECG analysis automatically to the acquired ECG waveform without reflecting al the status of the patient, thus the analysis result might be not identical with the physician’s diagnosis. So the final conclusion should be made by the physician through the comprehensive analysis and diagnosis in combination with the analysis result, patient’s clinical symptom and the other testing result.

2) Rhythm lead Mode

This model is the rhythm mode, the instrument can collect the designated rhythm leads (can be set in the parameter menu) of ECG data acquisition, the Length of acquisition time is 60 seconds or 120 seconds (set in parameter menu) rhythm-lead waveform data. When the ECG waveform data is collected completely, the system will automatically do the rhythm analysis, it can output the length of the rhythm which you have set and rhythm-lead ECG waveform analysis.

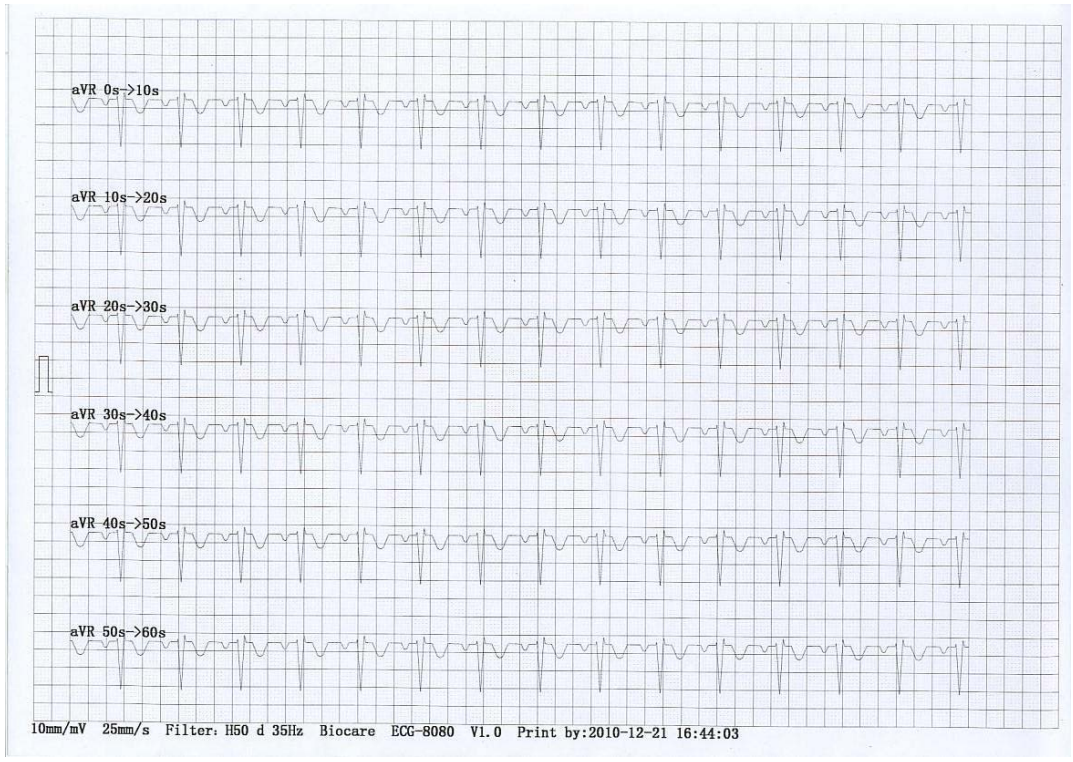
Using the touch pen or turn the “shuttle” to move the cursor in the menu option bar to select “rhythm” and press the “Enter” button, the instrument will connect the specified rhythm of the lead. The LCD will be displayed the working status of instrument as following:

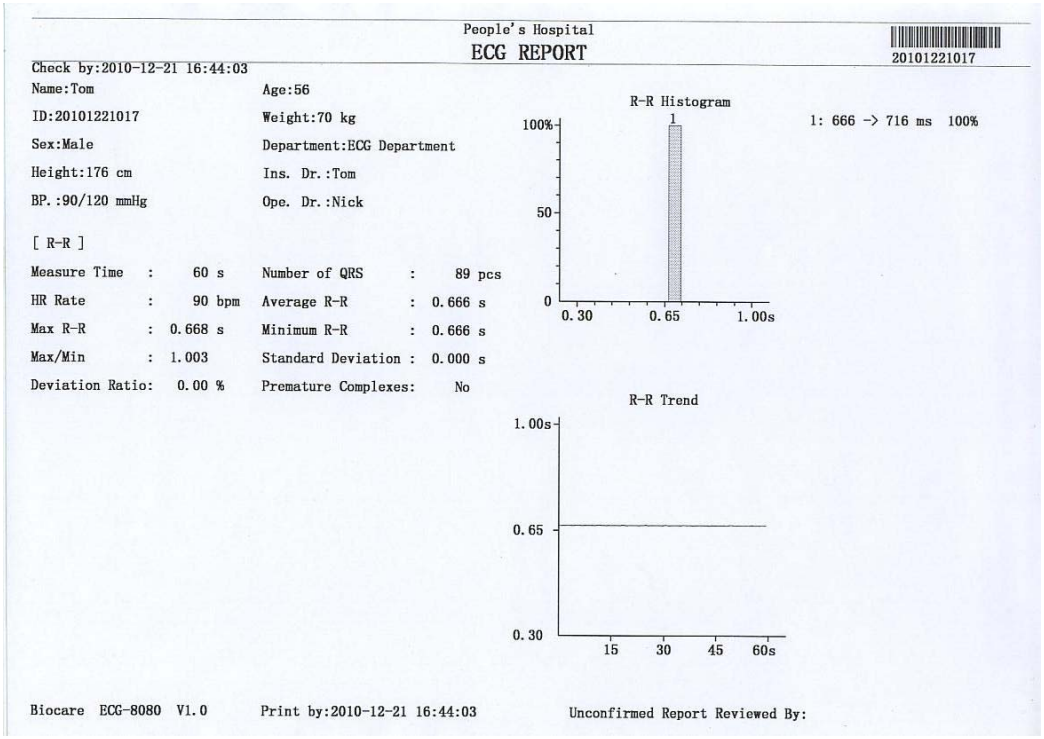
If the Instrument has completed the assigned lead ECG rhythm data's collection, it will automatic do the rhythm analysis, and the LCD will be displayed relevant results, as shown below:



The interface of the There are 6 options such as "Back", "Next", "print" "save", "upload", "ID" or "Exit". The detailed operation methods please refer to the "standard 12-lead mode"

Print the report of rhythm as shown ☹ in 60 seconds as an example):



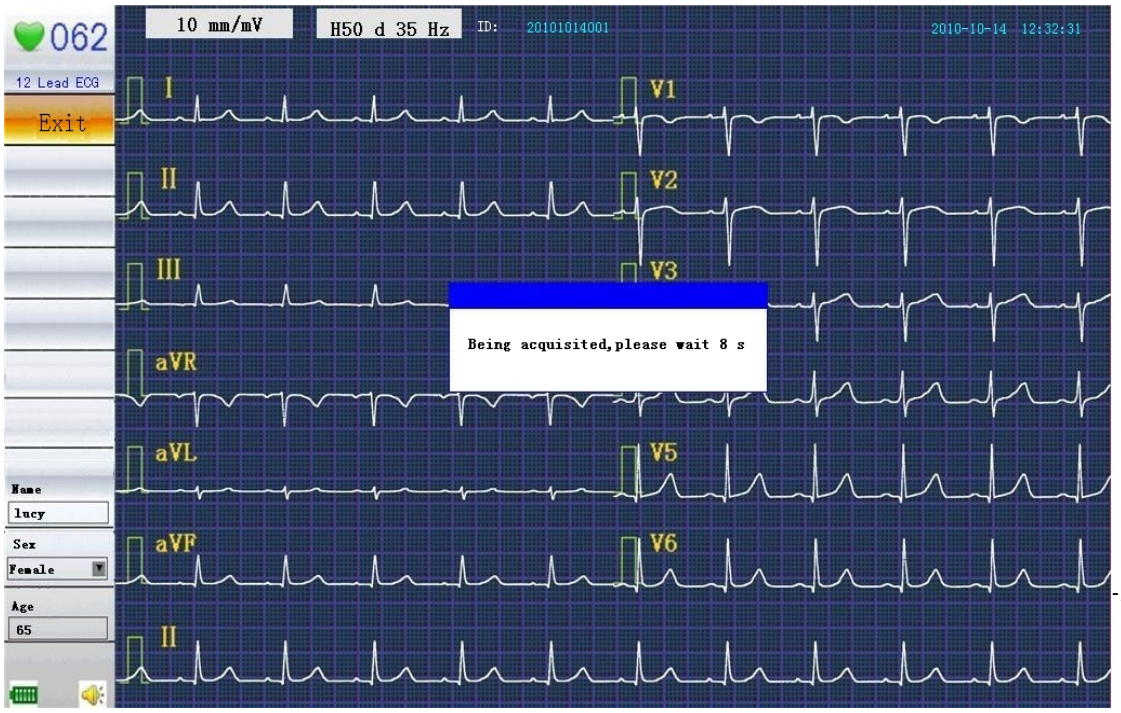


Note:

Barcode information on print report is the patient ID number, the barcode can be scanned by the scanner, please refer to 7.4 Barcode scanning.

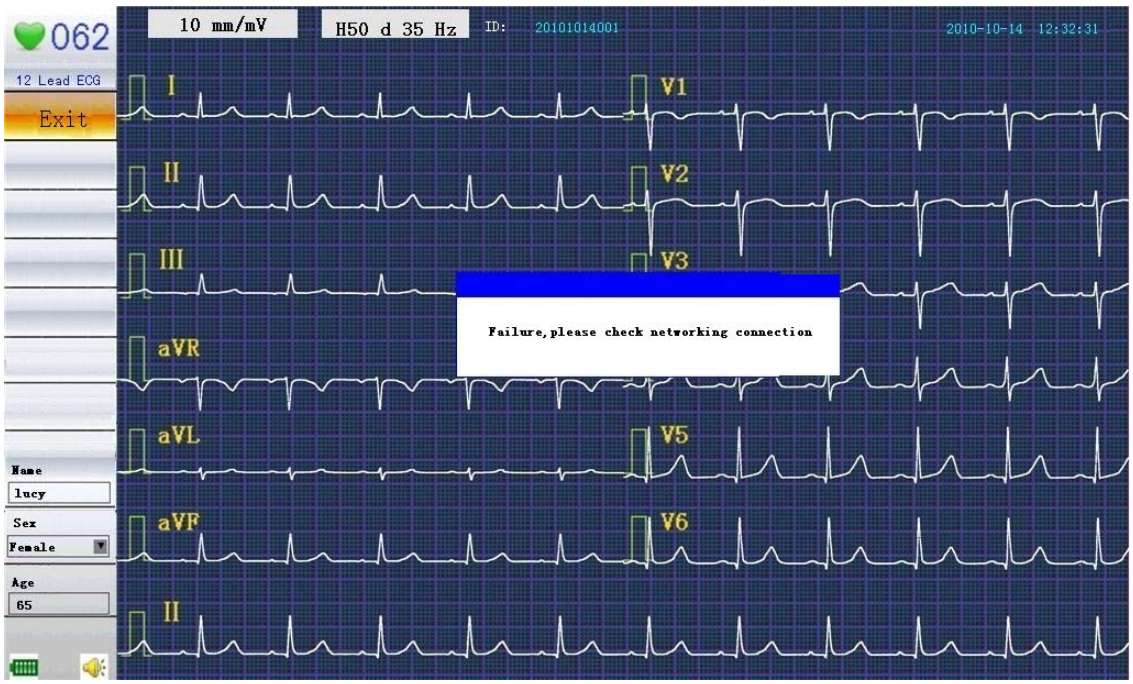
3) Upload

Using the touch pen or turn the "shuttle" to move the cursor in the menu option bar to select "Upload" and press the "Enter" button, then the LCD will be displayed the working status of instrument as following:



The instrument will analyze the collected data and saving, uploading.

If the device or network connection untreated well, it will be displayed the following information:

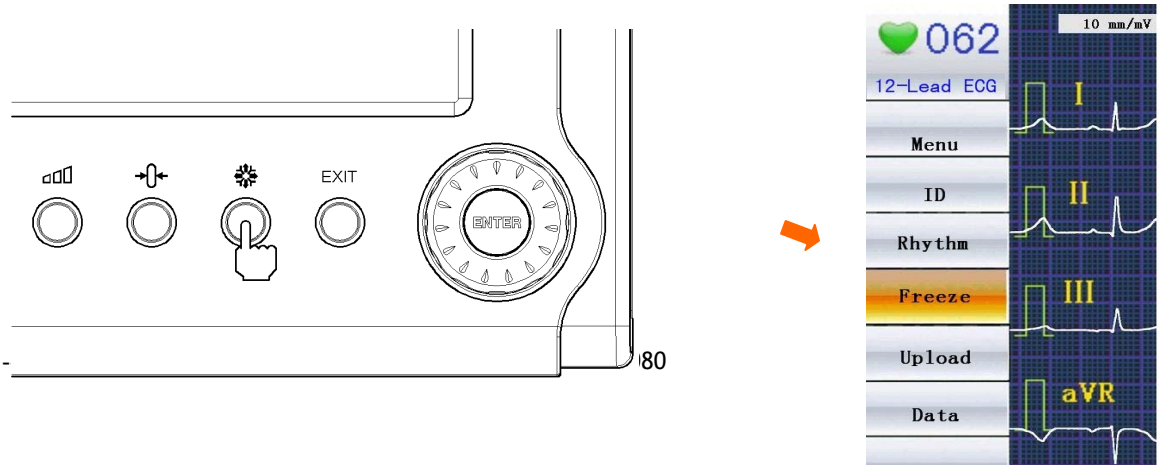


At this time, please check the adequacy of equipment and the network connections, if the network settings are correct, collect data and then re-upload.

5.5 Freeze Waveform

Only in the standard 12-lead mode, the freeze waveform function can be exit; Uses can analysis the frozen waveform data in the past 180 seconds.

In the standard 12-lead mode, if the acquisition wave length is not less than 12 seconds, you can press the ”Freeze” button on the instrument or turn the shuttle options screen to “freeze” and press “Enter” button, the operation icon displayed as shown below:



The main Screen will be displayd the following wave frozen picture:

Use the touch pen or turn the “shuttle” to move the cursor to select “ID”, “Back”, “Next,” “Report” or “Exit” operation.

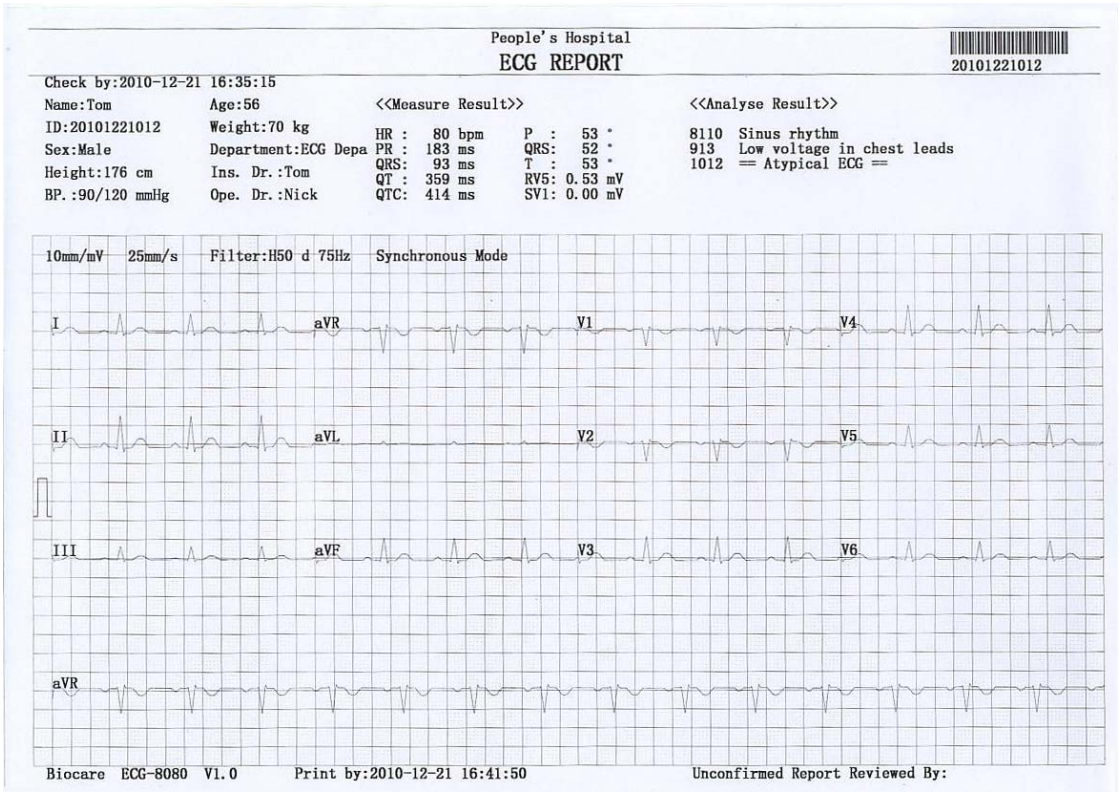
“ID” operation is the same as the “standard 12-lead mode “.

The “Back” and “Next” (red rectangular section) is tabbed browsing the frozen waveform data, each page showing the lead of 12 seconds of data, there are 15 page waveform data of these.

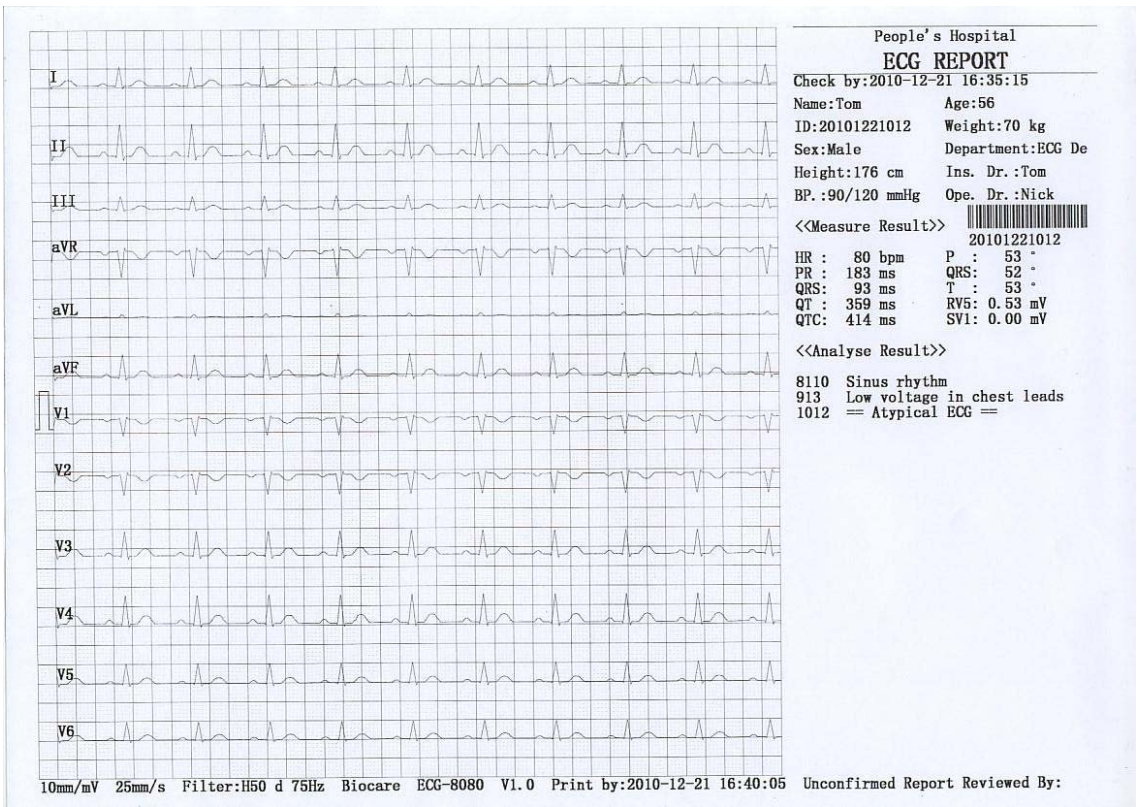
You can edit the patient’s name, sex, age settings and so on. Please reference to Chapter VII of the input ID-patient information input.

Select the “Report” and press the “Enter” button, the system will automatically analysis the current 12 seconds data.

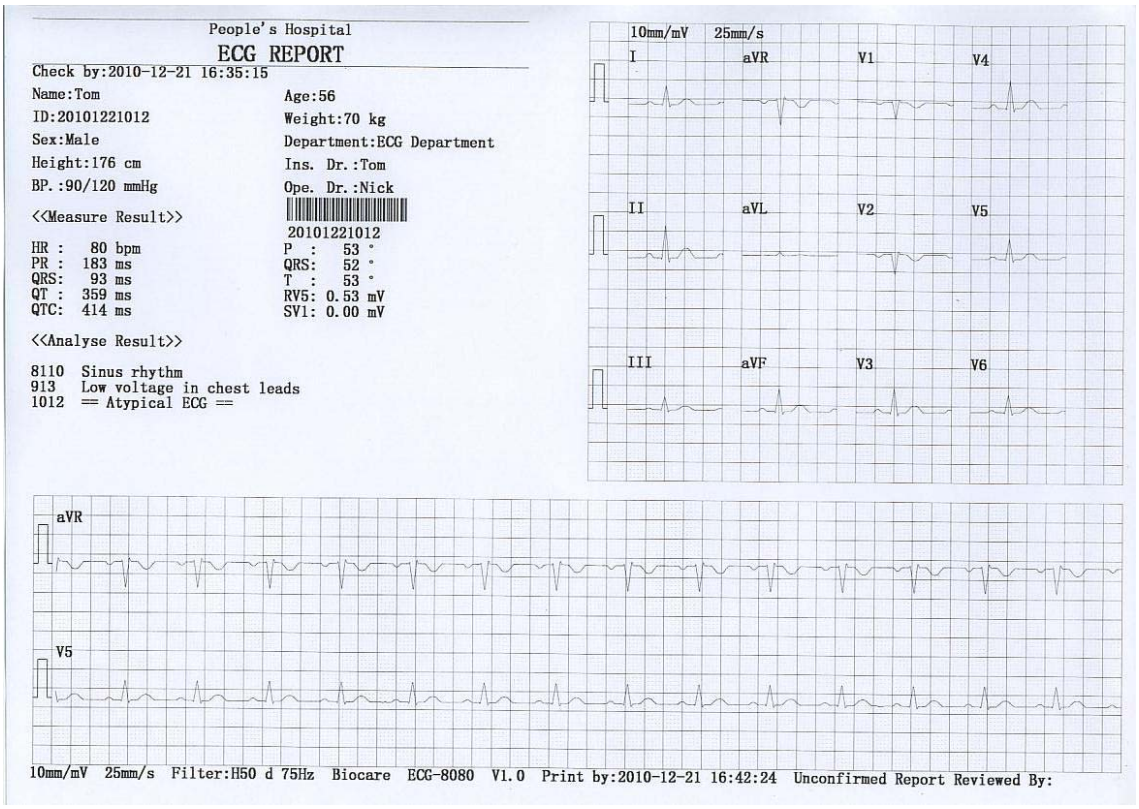
"3+1 channel" Print format as shown below



"12 channel" Print format as shown below



"Heartbeat" print format as shown below:



Note:

Barcode information on print report is the patient ID number, the barcode can be scanned by the scanner, please refer to 7.4 Barcode scanning.

5.6 Attention options

The following items should be given particular attention when performing the ECG waveform measurement and analysis

(1) If the myoelectricity or AC interference is significant, the identification for P wave and Q wave might be unreliable sometimes. The identification for ST section and T wave might be unreliable because of the baseline drift.

(2) If the ending point of S wave and T wave is bended and not clear, the measurement error might be caused sometimes.

(3) If the R wave is undetected because of QRS low voltage, the significant deviation might be caused in the heart rate measurement.

(4) The calculation of electrical axis of heart and the identification for the QRS dividing point might be unreliable because of low voltage of QRS

(5) Occasionally, the frequent (repetitive) ventricular premature beat might be detected as the representative beat.

(6) When the multiple arrhythmias occur simultaneously, the identification for P wave might be difficult, and the relative parameters might be unreliable.

Chapter 6 System Parameters Setting

With this instrument, you can set the various system parameters in the menu. The various parameters in the menu are defaulted as the factory values, and the users can set the parameters to be wanted values prior to ECG recording.

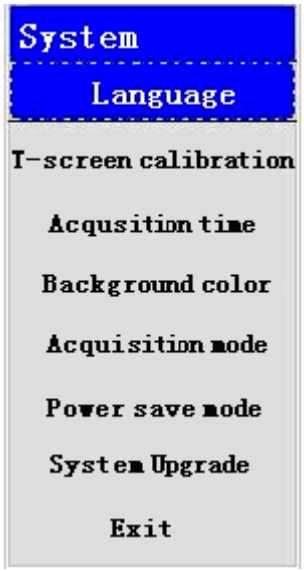
6.1 Main menu

After starting the instrument, you can use the touch pen or turn the shuttle to move the checkbox to the “Menu” option, and press the “Enter” button to enter into the screen of system menu as the following picture.

There are 9 sub-menu options: “System”, “Network “, “Audio”, “Rhythm”, “Print “, “AC Freq,” ”Select Storage”, “hospital information,” Device information“, “Exit” under this interface.

6.2 System setting

In the “Menu” screen, select “System” Setting (blue box), press Enter” button to enter into the system setting interface as shown below:



- **Parameter List**

Parameter	Setting Value	Defaulting Value	Comment
Language	Chinese/English/Russian	English	For setting the displayed language on screen
T-screen calibration	--	--	For the touch screen’s calibration
Acquisition time	1、2、3. 。。12	12	Setting the time of data collection
Background color	None, Blue, Red	Blue	Set the background of the screen grid color (restart it after setting)
Acquisition mode	Forward, Back	Back	Set up data acquisition sequence
Power save mode	Disable, Enable	Enable	The machine’s power-saving mode setting, open the access to power saving mode
System Update	--	--	Update software

6.3 Network setting

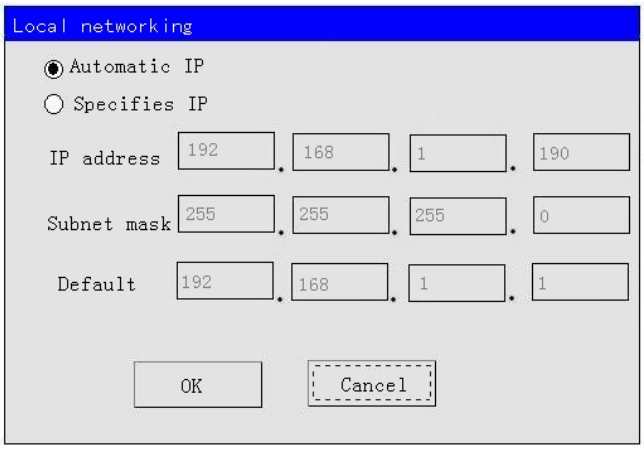
After the network cable connected well, in the “menu” interface, select the “Network” Settings (blue box), and press “Enter” button to enter into the Network setting interface as shown below:

■ **Parameter List**

Parameter		Setting Value	Defaulting Value	Comment
Network setting	Local Network	XXX.XXX.XXX.XXX	192.168.001.62	Set the local IP LAN
	Wireless Network	XXX.XXX.XXX.XXX	XXX.XXX.XXX.XXX	Wireless Network IP Address craw
	Network Server	XXX.XXX.XXX.XXX	202.96.134.133	Server Address settings

Local Network

In the Network Settings interface, select the “local network” with a touch pen or turn the shuttle and press the “Enter “button to enter into the Local Network setting as shown below:

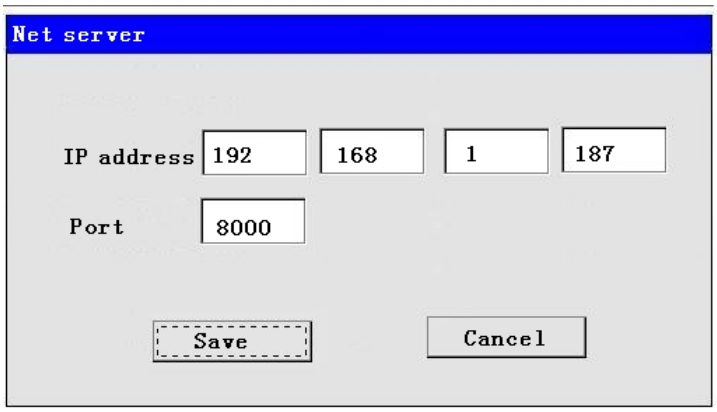


There are two ways to obtain IP addresses, one is automatically access：Select the option to automatically obtain IP address, and press “Enter” button, available IP addresses. Another is to specify the IP address, the need to set their own IP address, subnet mask, and gateway settings.

Click “OK” to Save Settings. Click “Cancel” to exit. The input method reference to Chapter 7 of **ID-patient information input**.

Network Server:

In the Network Settings interface, select the “network server” setting, and press “Enter” button to enter into the network server setting interface as shown below:



The input method reference to Chapter 7 of **ID-patient information input**.

After setting up the IP address and Port, please click “OK” to Save Settings. Click “Cancel” to exit.

6.4 Audio setting

In the “Menu” screen, select “Audio” Setting (blue box), and press the “Enter” button to enter into the Audio setting interface as shown below:

- **Parameter List**

Parameter		Setting Value	Defaulting Value	Comment
	Key Beep	off, tone 1, tone 2, tone 3	tone 2	Key beep tone setting

6.5 Rhythm setting

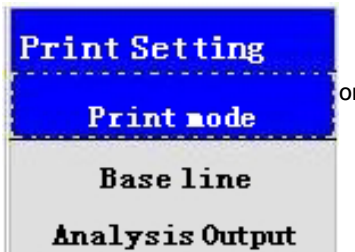
In the “Menu” screen, Use a touch pen or turn the shuttle to select “Rhythm” Setting (blue box), and press the “Enter “button to enter into the Rhythm setting interface as shown below:

■ **Parameter List**

Parameter		Setting Value	Defaulting Value	Comment
Rhythm setting	Rhythm lead	Ⅰ, Ⅱ, Ⅲ, Avr , Avl, Avf ,V1,V2,V3,V4,V5,V6	Ⅱ	Set the rhythm lead code
	Sub-Rhythm lead	Ⅰ, Ⅱ, Ⅲ, Avr , Avl, Avf ,V1,V2,V3,V4,V5,V6	Ⅱ	Set the sub- rhythm lead code
	Recording time	60S,120S	120S	Set the record time of rhythm lead

6.6 Print setting

In the “Menu” screen, select “Print” Setting (blue box), and press the “Enter” button to enter into the Print setting interface as shown below:



■ **Parameter List**

Parameter		Setting Value	Defaulting Value	Comment
Print setting	Print mode	12 channel, 3 +1channel, , heart print, R-R interval of Print	12 channel	Select print mode data acquisition
	Baseline width	1, 2, 3, 4	1	Select the width of the waveform baseline
	Analysis output	Off/On	On	Choose whether to print the analysis results

6.7 AC frequency setting

In the “Menu” screen, select” AC frequency” Setting (blue box), and press the “Enter” button to enter into the AC frequency setting interface as shown below:

■ **Parameter List**

Parameter	Setting Value	Defaulting Value	Comment
AC frequency	50Hz、60 Hz	50Hz	Select the AC frequency

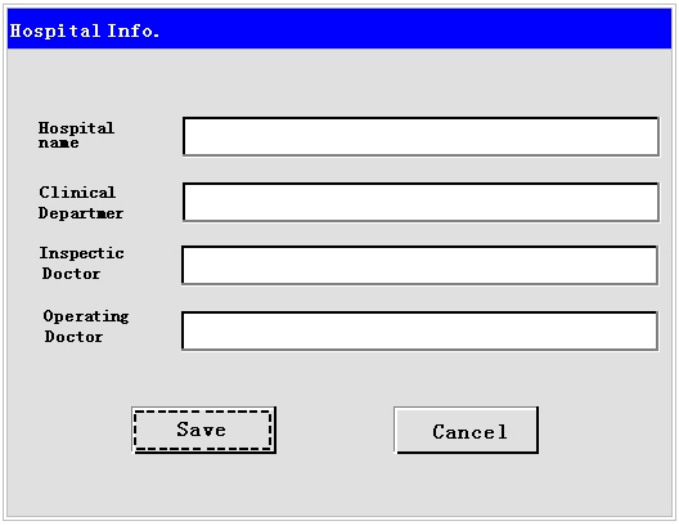
6.8 Select Storage setting

In the “Menu” screen, select “ Storage” Setting (blue box), and press the “Enter” button to enter into the Select storage setting interface as shown below:

Users can set the storied location of the data; there are three storage locations: memory, SD card, USB. Select the appropriate storage location; reliable storage device must be connected well. (SD card or USB)

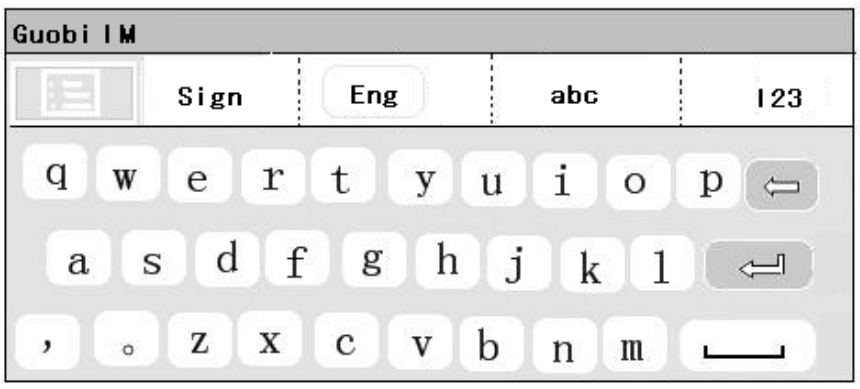
6.9 Hospital information setting

In the “Menu” screen, select “Hospital information Setting” (blue box), and press the “Enter” button to enter into the Hospital information setting interface as shown below:



Hospital name

Turn the shuttle or click the space with the touch pen; it will pop up a software Keyboard as shown below:



◆ keyboard input：

In the software keyboard, select “Eng” with a touch pen, enter the desired text spelling, press the “Enter” button to confirm input; You can choose the software keyboard icon in the top plate Symbols software interface, you can select the hide items (to hide the soft keyboard). Use the touch pen to select the “Eng”, may enter the letter; select “Sign”, can input the symbols; select “abc “ or “123” that can enter numbers and punctuation marks. Use the touch pen, you can move around the cursor position. Software key is the back plate on the grid button, click it to clear the front of a word or letter symbols. The icon is the “Enter” key, the icon is the space bar; click it to enter a space symbol. And click the “Save” button to save, click “Cancel” button to return.

Note:

You can use touch pen to move the location of the soft keyboard.

6.10 Device information

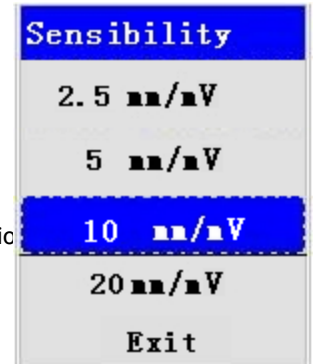
The Manufacturer, Device Name and Version of the instrument.

6.11 Sensitivity and the filter parameter setting

1. Sensitivity

Users can use a touch pen lightly to hit the sensitivity location in the interface.

And it will pop up as follows:



Users can set four different level sensitivity：2.5mm/mv，5mm/mv，10mm/mv，20mm/mv。

Press “Exit” option to exit setup interface.

2. filter parameter setting

Users can use a touch pen lightly to hit the filter parameter location in the interface. And it will pop up as follows:

Press “Exit” option to exit setup interface.

Filter parameter

Status or Control Items	Setting Value	Comment
Filter Setting	0.05-150Hz	All filters are off.
	H50 d	Only AC filter and drift inhibition（0.5 z High pass）are on.
	H50 d 75Hz	All filters are on, and the frequency of the myoelectrical filter is 0.5 -75Hz

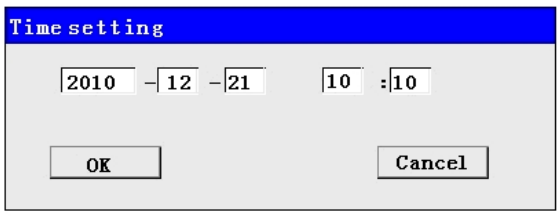
	H50 d 35Hz	All filters are on , and the frequency of the myoelectrical filter is 0.5 -35Hz

Note:

- **The "H60" in the "H60 d 75Hz" is changeable based on the set AC frequency. For example, H50 d 75Hz might be displayed.**
- **AC frequency setting must match with the AC frequency of the local, if set incorrectly, it will affect the result signal acquisition and analysis.**

6.12 Date and time setting

Users can use the touch pen lightly above the date and time parameters, and then it will pop up the following interface:



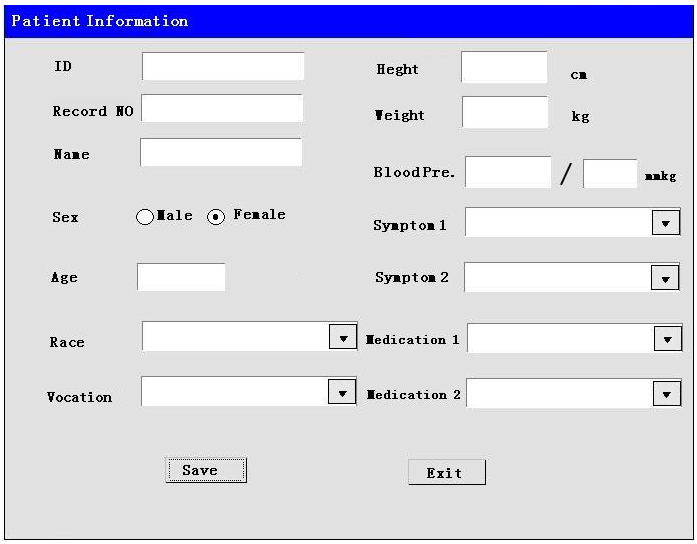
The Time setting interface will be displayed (The input method referred to the Hospital information input), after setting, click the “OK” to save, and click the “cancel” to cancel the time setting.

Chapter 7 Patient Information and Data Administration

In the Checking interface or analysis report interface, ECG waveform, the results and patient electrocardiogram data constitute a file, which can be saved in memory for easy data management and query.

7.1 Inputting of Patients' Information

In the ECG measurement interface, use the touch pen, or turn the shuttle to move the cursor to the "ID" and press the "enter" button, the instrument goes into the "ID" interface; you can input the detailed patient information in this interface. For instructions and the screen displays as the following picture:



Scan the barcode for patient ID number, patient's ID number will be uploaded in the patient information window, ID number is automatically uploaded.

- **Patient information parameter list**

Parameter	setting	default	explain
Birthday	XXXX Y XX M XX D	Patient date of birth	Based on the actual input
ID NO	Any numbers or letters	None	Based on the actual input
Record NO	Any numbers or letters	None	Based on the actual input
Name	Any characters, letters or numbers	None	Based on the actual input
Sex	Male and female	Male	Select the sex of the patient
Race	Asian, European, African, American, Pacific	Asian,	Based on the actual input
Vocation	Unknown 0¯8	Unknown 0	Select the relevant job description
Height	1~250cm	175cm	Based on the actual input
weight	1~400kg	70kg	Based on the actual input
D.O.B	1~998 / 1~998mmHg	75/120mmHg	Based on the actual input
Symptom1/2	Unknown 0¯8	Unknown 0	Select the relevant descriptions of the symptoms
Medication 1/2	Unknown 0¯8	Unknown 0	Select the relevant drug description

■ **Parameter setting method**

1. ID NO 、Record NO 、Name

Chinese input:

◆ keyboard input:

In the software keyboard, select “Eng” with a touch pen, enter the desired text spelling, press the “Enter” button to confirm input; You can choose the software keyboard icon in the top plate Symbols software interface, you can select the hide items (to hide the soft keyboard). Use the touch pen to select the “Eng”, may enter the letter; select “Sign”, can input the symbols; select “abc “ or “123” that can enter numbers and punctuation marks. Use the touch pen, you can move around the cursor position. Software key is the back plate on the grid button, click it to clear the front of a word or letter symbols. The icon is the “Enter” key, the icon is the space bar; click it to enter a space symbol. And click the “Save” button to save, click “Cancel” button to return.

Note:

You can use touch pen to move the location of the soft keyboard.

2. Race, Vocation, Height, Weight, Blood pressure,Symptom1/2,Medication 1/2

Users can use the touch pen of rotate the shuttle to move the cursor to point to set the parameters, press the “Enter” button to select the parameters , then turn the shuttle to change the parameter settings, at last press the “Enter” button to complete the parameter settings. Click the “Save” button to save, click “Cancel” button to return.

3. Age,、Height 、Weight、Blood pressure

Users can turn the Shuttle or the touch pen to move the cursor pointing to set the parameters to complete the input, turn the Shuttle to select the next setting, click the “Exit” to exit the parameter setting. Finally, click “Save” to save.

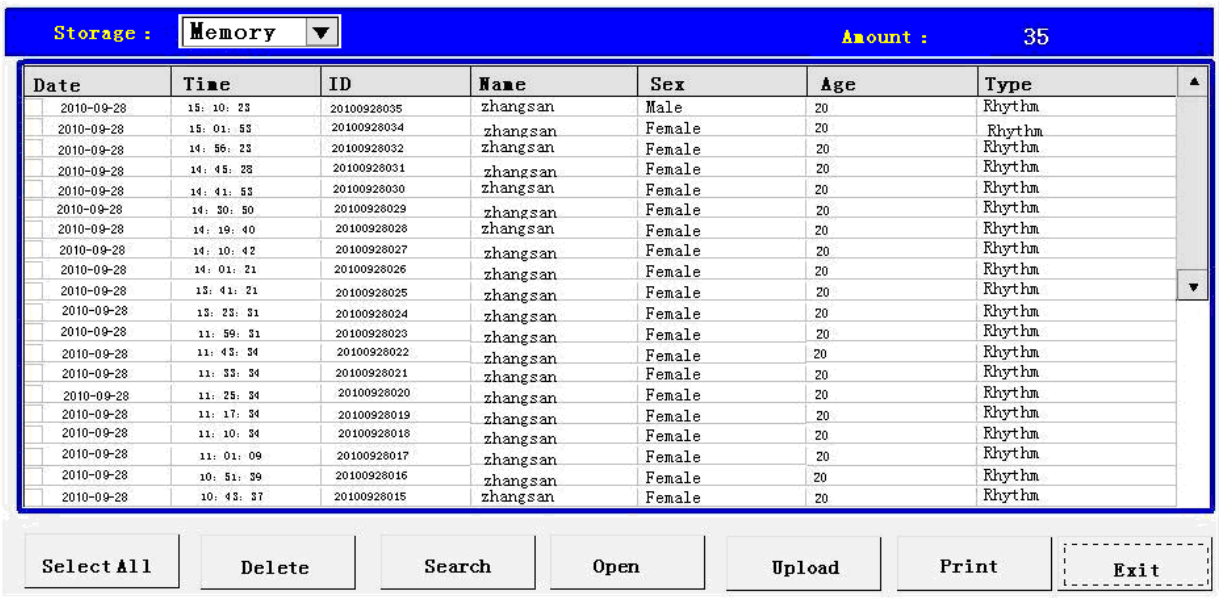
1 **Sex**

Select Male or Female.

7.2 Database Administration

ECG-8080 can make the waveform, patient information and analysis results as a file stored in memory or SD card or USB hard drive for future data query and management purposes.

In the “Menu” screen, select “Data Management” (blue box), click “OK “ into the data management interface as shown below:



Users can do the “select all”, “delete”, “search”, “Open” “Upload”, “Print” operation. (Darker background color for the currently selected operation). If you want to exit the data management interface, select the “Exit”

In the top of the data management interface, you can use the touch pen or rotate the shuttle to choose data storied location: memory, SD card or USB, for example, if you want to open the memory data, please select the “memory”;

When the files stored in more than 20 (for a maximum of 20), you can use the right side scroll bar in the screen to moved up and down.

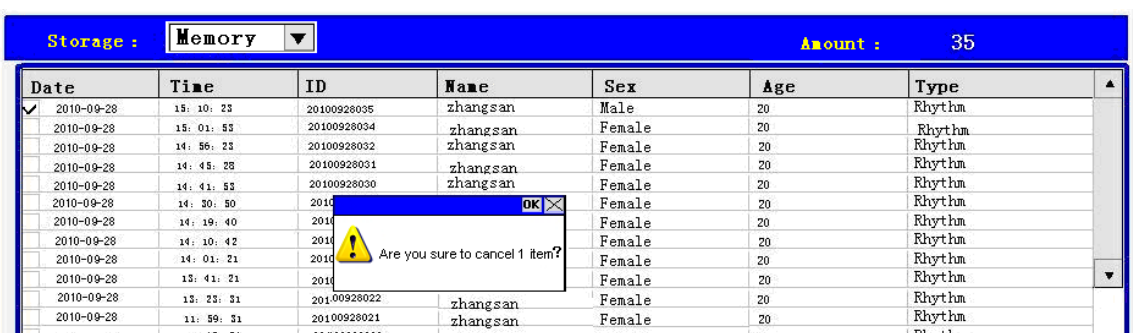
■ Open File

Turn the shuttle or using the touch pen to select “Open Wave”, press the “Enter” button, you can browse the appropriate file, as shown below:

In this interface, you can choose the “upload”, “Next,” “Edit,” “print” “save” or “exit” of the operation. Detailed operations, please refer to the “standard 12-lead mode”

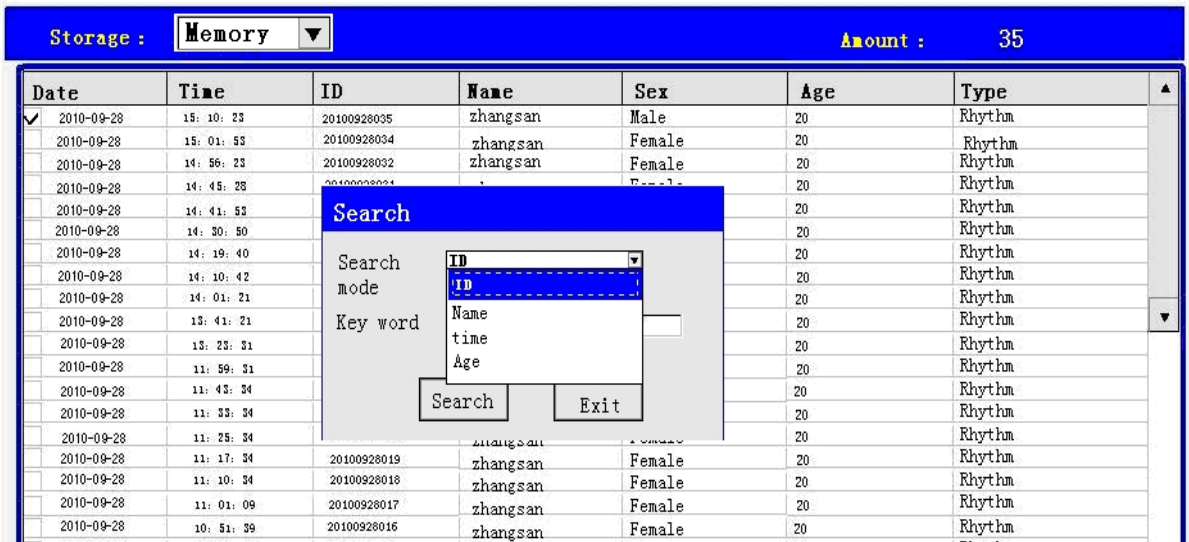
- **Delete File**

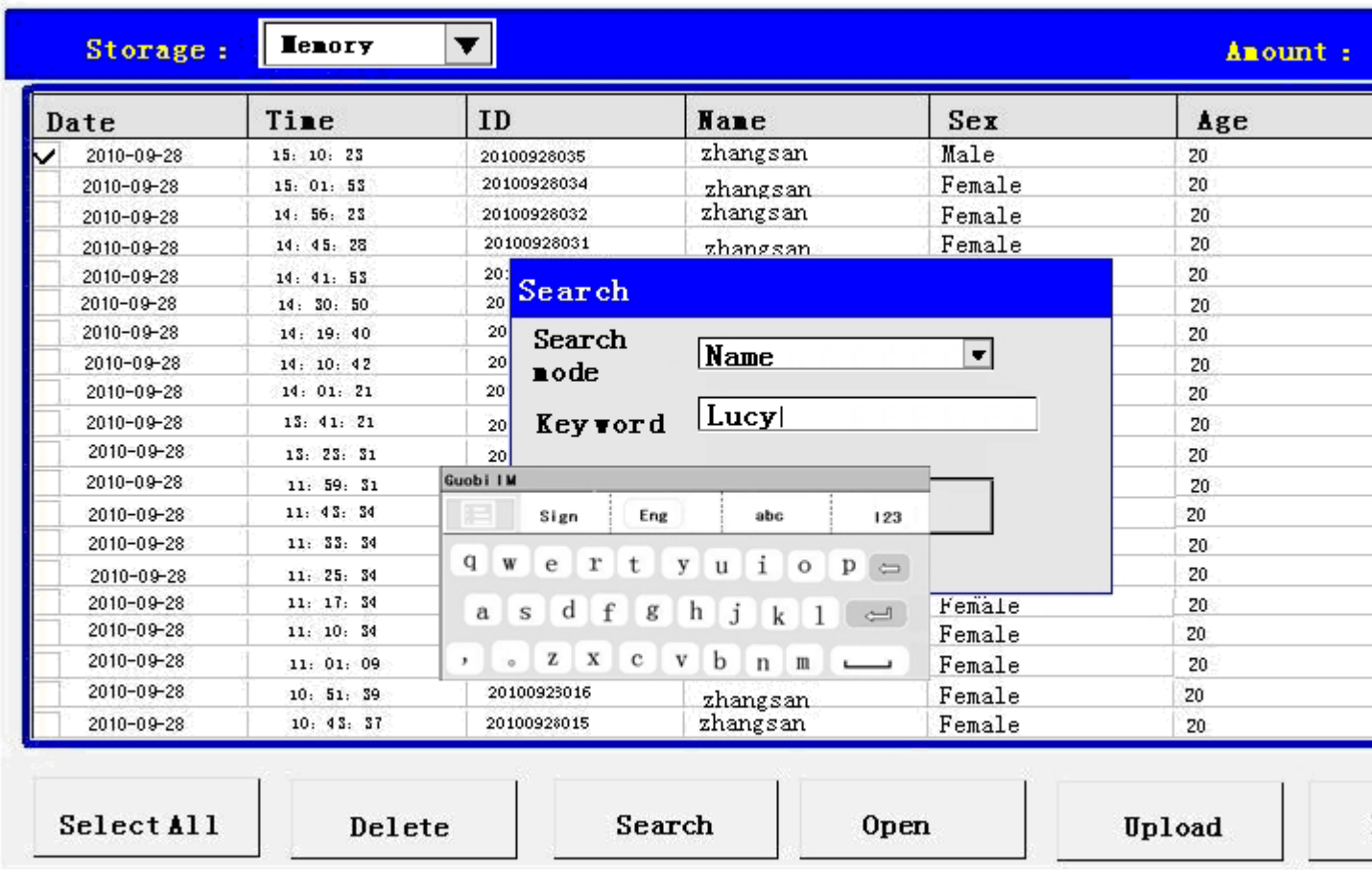
Use the touch pen to select a data, and then select “Delete”, it will appear an warning to confirm the removal of the prompt. Select “Yes”, you can delete the selected file。If you delete this record, the later data storage will be stored in the deleted position. If you delete the record, this record will not recover, please exercise caution!



- **Search File**

  Select “Search” option, press “Enter” button to enter into the file search interface; here you can use the ID, Name, and Date and Age s of four methods to find the required files.



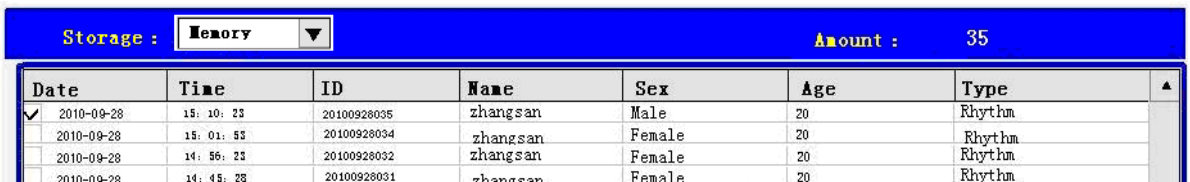


The edit method please refer to Chapter 7.1; when the name is edit well, press “Enter “button, then rotate the shuttle moving the cursor to the “Search” option, then press “Enter” button again, the system will automatically find the appropriate file, if it found ,the list of files would be displayed, , or it said “not found.”

Refer to the Name search operation when you want to search the files by the ID and Age.

Date search

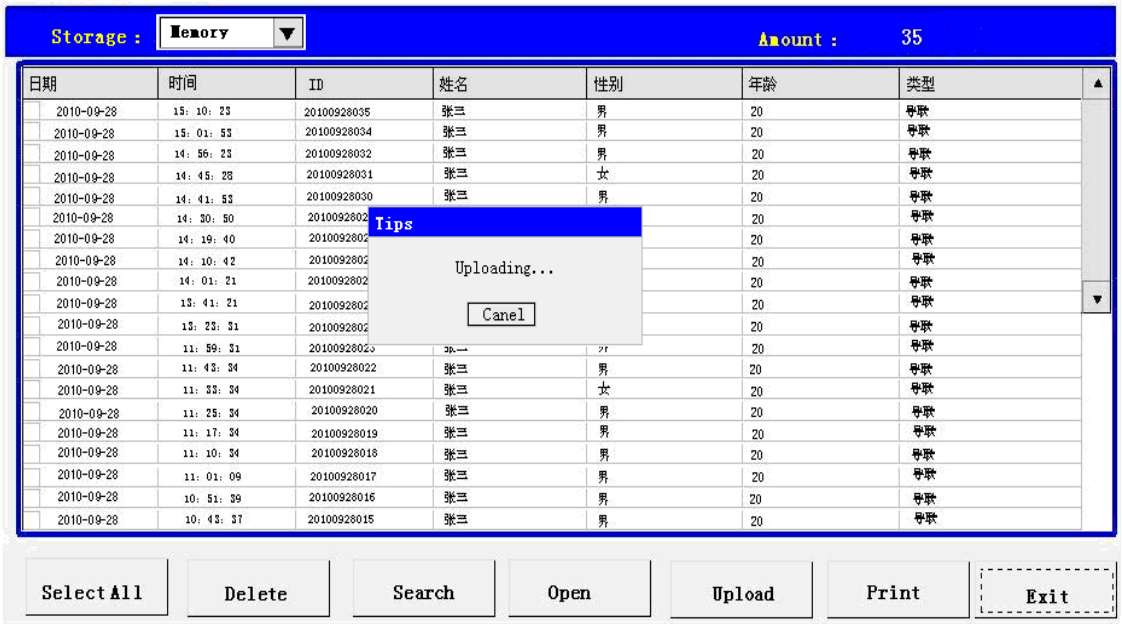
When you search files by the date, move the cursor on the “Date” option, then press the “Enter” button, you can see the screen as follow.



When the Date is edit well, press “Enter” button, then rotate the shuttle moving the cursor to the “Search” option, then press “Enter” button again, the system will automatically find the appropriate file, if it found ,the list of files would be displayed, , or it said “not found.”

- **Upload**

Select “Upload” option, press “Enter” button to enter into the file upload interface, as shown below:



If you want to see the detailed operations, please refer to Chapter7: 7.3 Data Transmission.

■ **Print**

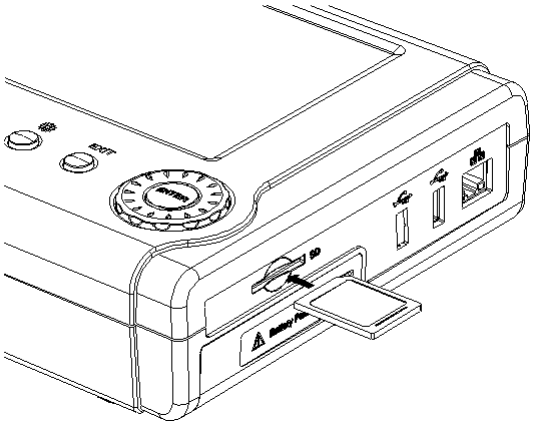
Select “Print” option, if the printer is connected in the right circumstances, the selected data can be directly printed the ECG report.

Note:

If you want to exit the operation, please press the “EXIT” button to exit.

SD card plugging and unplugging

As the following picture, position the SD card to the slot and plug it into the slot with the front surface of card upward till the sound of “Ka” is heard which indicated that the SD card has been plugged into the slot correctly.



After data storage , remove the SD card by pressing the margin of SD card with the fingers and push it slightly inward, then the SD card will leave the slot automatically.

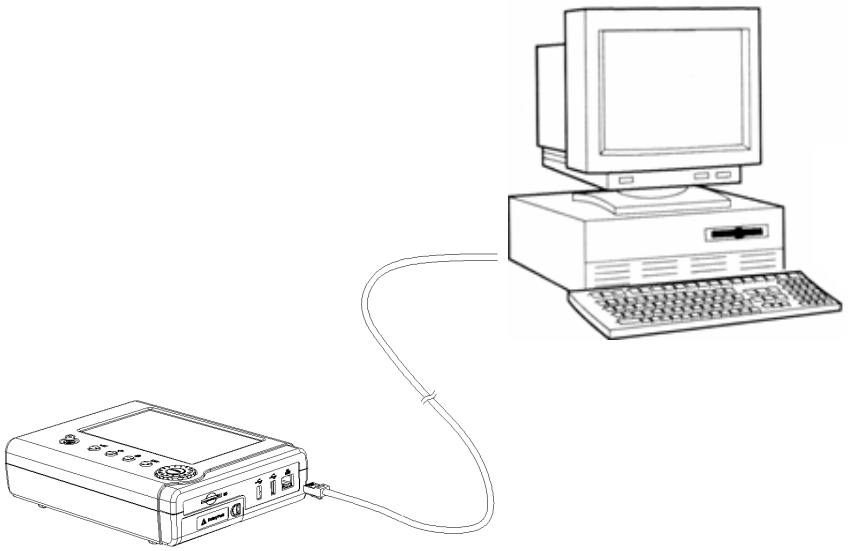
7.3 Data Transmission

This instrument can be connected onto the PC through the LAN port to upload file and process the ECG data.

Before using the function of upload, you must set down the “Local” and “Server” items in

the “NET IP Address”, and make the local and server address in the same sub-network segment. (e.g. local address: 192.168.001.xxx, server address: 192.168.001.xxx). You also need to make the server address in the instrument same to the IP address in the receiving computer. The instrument should be connected onto the PC through LAN port, and the software and driver for ECG administration should be installed in the PC before using it. (Please refer to the instruction for ECG administration software for the detailed operation.)

- **Connection for LAN port**



As shown in the right side of the instrument’s network interface to plug network cable, please use Category 5 UTP cable.

7.4 Barcode scanning

The instrument supports barcode scanning.
Through the USB interface to connect the scanner with the ECG-8080 instrument correctly, scanning the existing patient ID number barcode, barcode corresponding to the patient ID number will be transmitted ECG instrument.

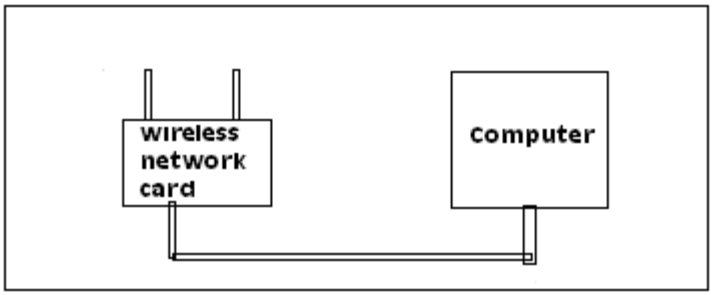
Note:

- **When server address changed and correctly connected, if upload unsuccessfully, please reboot the instrument or the ECG administration software.**
- **The ECG administration software is optional for users to purchase, and if needed, please contact the post-sale department of our company for purchasing.**

7.5 Wireless Setting

The instrument can also be connected to a computer through a wireless router (has ECG management software) for data uploading, editing the data for printing on the electrocardiogram, management, and diagnostics, local area network data transmission and sharing.

1. With a wireless connect wireless router to computer, such as: set the computer's IP address is 192.168.0.148 Mask: 255.255.255.0, gateway is set to: 192.168.0.1.



2. Open the ECG-8080 instrument, select the menu - network setting - server address, such as setting the server address is 192.168.0.148, the address of the machine automatically.

3. Connected with the USB wireless card, when the wireless network card light always lights, or fast flashing, indicating that the wireless card is working.

4.. Running ECG management software in the computer, after entering the interface, it can receive data, select upload, the data will be transmitted to the ECG management software which in the computer's wirelessly.

Note:

The instrument and a wireless router can not be too far away, as several rooms (depending on the environment), when the wireless card light is off, or long flashes (4,5 seconds, flash once, regular blinking), indicating that the wireless network card is not working properly, please make sure:

1. Whether the router power is normal;

2. Whether the ECG-8080 is within range;

Solution:

Open the power of the route, making the effective range of ECG, or re-inserting the wireless Network card into the electrocardiogram instrument..

Chapter 8 Servicing and Maintenance

8.1 Charging, Capacity Displaying and Replacement of Battery

ECG-8080 built-in high-performance high-capacity rechargeable lithium battery (14.8V/4400mAh), full of power could be used for> 8 hours. The instruction for charging, capacity displaying and replacement of battery is given as follows:

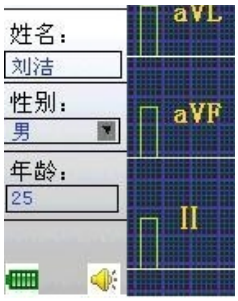
1） Battery charging

ECG-8080 instrument should be offline charging. During the charging time, the battery required to remove, the machine is equipped with a special charger (charging specific steps see chapter IV). At least every three months, the battery should be charged and discharged for one time.

2） Battery capacity displaying

When using the battery as the power supply, a symbol indicating the battery capacity will

be displayed in the top arrow on the LCD screen as the following picture after starting the instrument. This symbol can indicate the battery capacity in 3 different shapes. See the following picture for details.



：The battery charge is sufficient

：More than half the battery power consumption, selectable charge；

：Complete consumption battery faster, please charge

3） Battery replacement

The battery should be replaced by the servicing personnel and according to the following procedures

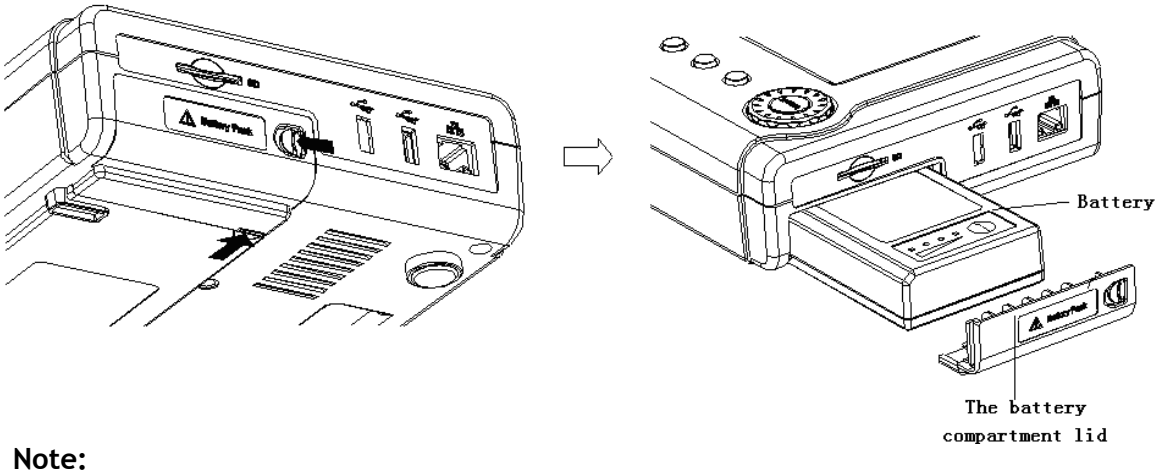
(1) Shot down (press the on / off button for more than 1 second);

（2）According to the following prompt, press and hold the battery doors of the thumb on the push button to the direction of the arrow, while the index finger in the bottom of the instrument to pull out the arrow protruding Office, you can open the doors of the battery;

（3）Unplug the battery plug and take out the batter

(4)Replace the existing battery with a new one, Plug in the battery socket with attention to polarity and good connection;

（5）Fix the battery compartment door.



Note:

- **Do not connect the positive and negative electrodes of the battery directly of else it may cause the fire.**
- **Do not put the battery closely to the open fire or else it may cause the explosion.**
- **Unauthorized disassembly is not allowed.**
- **Handle the battery cautiously, and do not drop it on the floor at discretion or hit the other articles.**

8.2 Instrument maintenance after using

The following maters should be given particular attention after using the ECG instrument:

(1) Press the ⏻ (ON/OFF) button on the control panel to set the instrument in the stand-by status.

(2) Hold the plug to pull off the power supply cable and the lead lines instead of holding the cable.

(3) Clean up the instrument and accessories, then place the dust cover on it.

(4) Keep the instrument in the dry and cool environment. Prevent it from intense shock when moving it.

(5) Do not soak this instrument into the detergent when cleaning it. Please cut off the power supply first when cleaning the outer shell of the instrument. Please clean the instrument with the neutral detergent instead of using the detergent containing alcohol or using the sterilizer.

8.3 Inspection and maintenance of lead lines and electrodes

1 lease inspect the continuity condition of the lead lines regularly, since the damage of any one line among them will cause the false waveform of corresponding lead or the entire lead in the electrocardiogram. The lead lines can be cleaned with the water and soap as well as sterilized with 75% alcohol (do not soak the lead lines into the liquid for sterilization).

Note: The electric resistance of the lead line with the protective function of anti-defibrillation is 10KΩ approximately.

Symbol for connector plug	R	L	F	RF	C1	C2	C3	C4	C5	C6
Position for plug and pin	9	10	11	14	12	1	2	3	4	5

2. Bending the lead line in the sharp angle or knotting will decrease the service life of the lead line, thus please perform the electrodes connection after tidying the lead line as possible.
3. The electrodes should be stored well. After using for long term, the oxidation color change of the electrodes may occur due to corrosion and so on, and the electrocardiogram may be affected. If this happens, please replace the electrodes in time.

Chapter 9 Common Fault and Troubleshooting

9.1 Machine of Death

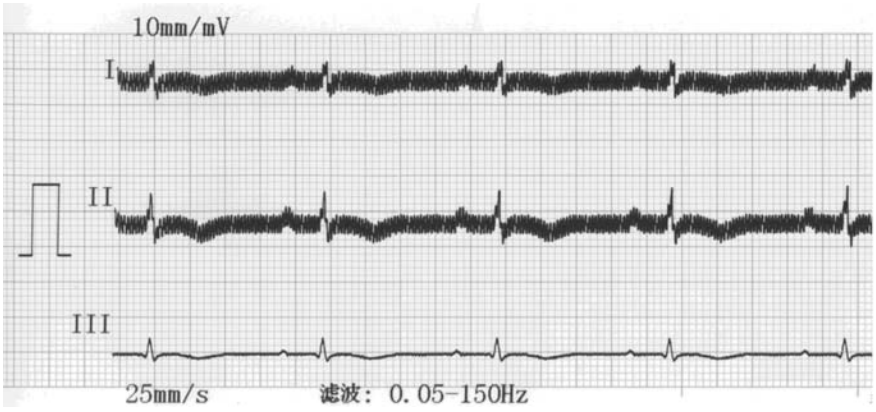
System software conflict caused by the instrument operator crashes occur, the screen display still, the operation button is invalid, please press ⏻ button for 3 seconds and release, it can force the shutdown, reboot the instrument back to normal. If this fault occurs frequently, please contact our service department or the designated service point of contact.

9.2 Malfunction of the silicon rubber buttons partially or entirely

It might be caused by the loosened-off connector for the silicon rubber button circuit board and the main control board. In this case, the top cover of this instrument should be opened to reconnect the connector of the silicon rubber button circuit board and the instrument main control board by the professional servicing personnel .In addition, please check if any stuck key appears because of aging, and if it is , it should be addressed. If the problem still exits after addressing by the above methods, please contact the service department of our company or the designated maintenance stations.

9.3 AC interference

Phenomenon: The regular interference with a certain degree of amplitude occurs during the electrocardiogram tracing, and the shake of the baseline can be observed obviously as the following electrocardiogram:



(1) Is the grounding of the ECG instrument reliable?

(2) Is the connection of electrodes and lead lines correct?

(3) Are the electrodes and the skin coated with the electrodes cream?

(4) Is the grounding of the metal bed reliable?

(5) Does the patient contact the wall or the metal part of bed?

(6) Does the patent contact the other patient?

(7) Is there any high power electrical equipment working around this instrument such as the X-ray or the ultrasound device?

(8) Does the patient wear any ornaments made of glass or jewel?

Note:

If the AC interference can still not eliminated after taking the above mentioned measures, the AC interference filter can be used for filtering the interference.

9.4 Myoelectric interference

Phenomenon: There is irregular shake in the recorded electrocardiogram waveform as the following picture:

This phenomenon may be caused by the following reasons, please check them one by one to eliminate it :

(1) Is the examination room comfortable?

(2) Is the patient nervous?

(3) Is the bed too narrow?

(4) Is the patient speaking during the recording?

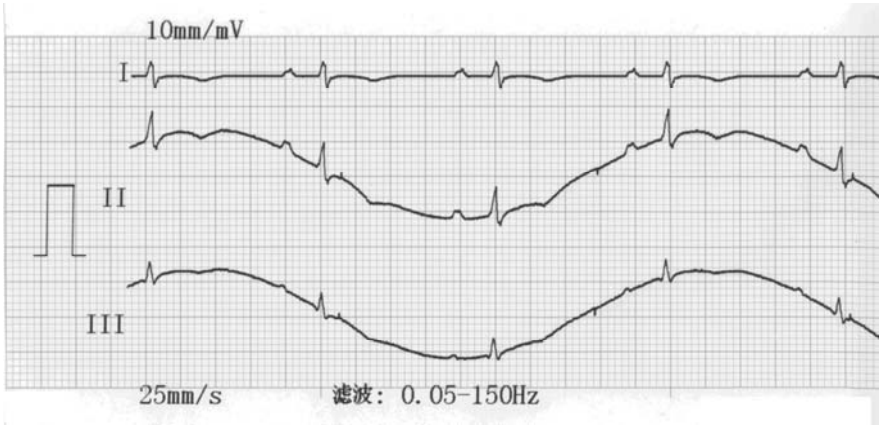
(5) Are the electrodes clips of the limbs too tight?

Note:

If the interference can still not be eliminated after taking the above mentioned measures, the myoeletric filter can be used for filtering the interference. When using this filter, there will be slight attenuation of the recorded electrocardiogram waveform, particularly for the R wave.

9.5 Baseline instability

Phenomenon: There is irregular up and down shift in the baseline of the recorded electrocardiogram waveform as the following picture:



This phenomenon can be leaded by the following reasons, and please check them one by one to eliminate it:

(1) Are the electrodes connected well?

(2) Is the connection of the lead lines and the electrodes well?

(3) Are the electrodes and the skin of patient clean?

(4) Are the electrodes and the skin of the patient coated with the electrodes cream?

(5) Is the patient moving his or her body or breathing during the recording?

(6) Are the new electrodes and the old electrodes used together?

Note:

If this phenomenon can still not be eliminated after checking the above mentioned reasons, the baseline drift filter can be used for filtering.

Appendix A Package and Accessories

A1. Accessories accompanying the instrument

The following items should be included in the intact package then the instrument is delivered from the factory:

Name	Unit
Instrument of ECG-8080	1 unit
Packing List	1 copy
Qualified Certificate	1 copy
Collection Box	1 piece
Grounding Cable	1 piece
Power adapter	1 piece
Touch pen	1 piece
Power Cable	1 piece
Limb Electrode	4 pieces
Chest Electrode	6 pieces
Operation Manual	1 copy
Paper shaft	1 piece
Patient cable	1 piece
Battery	1 piece

A2. Matters needs attention

1 Operating as the tips given on the package box when unpacking.

2 Please check the accessories and accompanying document according to the package checklist after unpacking before inspecting the instrument.

3 If the contained items do not accords with checklist or the instrument can not work normally after unpacking, please contacting the marketing department or the service department immediately.

4 Please use the accompanying accessories provided by out company, of else the performance and the safety of this instrument might be affected. Please consult the service department of our company first when using the accessories provided by the other companies.

5 For immediate service provided by our company, please fill out the maintenance warranty card in detail (the copy) and send it to our company.

6 The package box should be kept well for the regular inspection or maintenance for the instrument.

Appendix B Technical Specification

B.1 Specifications

1 Main unit

Lead:	Standard 12-lead	
Acquisition mode	Simultaneous 12-lead acquisition	
Recording format	Standard 12 lead mode/transport mode/rhythm mode	
Recording mode	Automatic	Record in appropriate format and automatic lead switch with measurement and analysis function
Long term recording	Record for a long term (60,120 sec.) and rhythm analysis	
Measurement parameters:	Ventricular rate, PR interval, QRS time limit, QT/QTC interval, P/QRS/T axis, RV5/SV1 amplitude and RV5+SV1 amplitude	
Filters	AC, drift and myoelectric filters	
Input CIR current	≤0.1μA	
Input impedance	>50MΩ	
Patient leak current	<10μA	
Time constant	≥3.2s	
Frequency response	0.05～150Hz	
Noise level	<15μV_{p-p}	
Sensitivity threshold:	≤20μV	
Sensitivity	Four levels as 2.5，5，10，20mm/mV	
Calibration voltage	1mV±3%	
Input circuit:	Floating circuit input	
Paper speed	Rhythm mode: rhythm recording time is set to 60 seconds, the paper speed is 25mm / s, rhythm recording time is set to 120 seconds, the paper feed speed is 12.5mm / s. Paper speed is 25mm / s under the other modes.	

1. others:

Lead lines	ECG-9801.F01.00
Display on LCD	The whole instrument work status, time, heart rate, and

	with the backlight
Safety Classification	GB 9706.1-2007 class Ⅱ Type CF

B.2 Dimensions and weight

Length × width × height	230mm×180mm×61mm
Weight:	About 2 kg

B.3 Environment requirements

1	Transportation	
	Environment temperature	-20℃—+55℃
	Relative humidity	25%—95% (No condensation)
	Air pressure	50KPa～106KPa
	In accordance with the requirements stipulated in the contract order, the transport process to prevent rain and sun.	
2	Storage	
	Environment temperature	-10℃—+40℃
	Relative humidity:	25%—80%
	Air pressure	50KPa～106KPa
	The packaging of ECG stored in the non-corrosive gases and well-ventilated room.	
3	Using	
	Environment temperature	+5℃—+40℃
	Relative humidity:	25%—95%
	Air pressure	70KPa～106KPa

Appendix C Output Code and Interpretation of Analysis

8 Arrhythmia

Code No.	Description
8002	Marked rhythm irregularity
8110	Sinus rhythm
8102	Sinus arrhythmia
8108	Marked sinus arrhythmia
8120	Sinus tachycardia
8130	Sinus bradycardia
8200	Atrial rhythm
8210	Atrial fibrillation
82101	Atrial fibrillation with rapid ventricular response
82102	Atrial fibrillation with slow ventricular response
82103	Atrial fibrillation with aberrant conduction, or ventricular premature complexes
82108	Atrial fibrillation with rapid ventricular response with aberrant conduction
82109	Atrial fibrillation with slow ventricular response with ventricular premature complexes
8220	Atrial tachycardia
8250	Atrial flutter
82503	Atrial flutter with aberrant conduction or ventricular premature complexes
82505	Cannot rule out atrial flutter
8300	Junctional rhythm
8320	Junctional tachycardia
8400	Supraventricualr rhythm
8420	Supraventricular tachycardia
8430	Supraventricular bradycardia

8470	with occasional supraventricular premature complexes
8474	with frequent supraventricular premature complexes
8475	with frequent supraventricular premature complexes in a pattern of bigeminy
8500	Ventricular rhythm
8520	Ventricular tachycardia
8570	with occasional ventricular premature complexes
8574	with frequent ventricular premature complexes
8575	with frequent ventricular premature complexes in a pattern of bigeminy
86006	Electronic atrial pacemaker
86007	Electronic ventricular pacemaker
8901	Undetermined regular rhythm
8902	Undetermined rhythm
8970	with occasional ectopic premature complexes
8974	with frequent ectopic premature complexes
8975	with frequent ectopic premature complexes in a pattern of bigeminy

6 AV Conductive Defect

Code No.	Description
611	Possible third degree AV block
621	Second degree AV block, Wenckebach type
622	Second degree AV block, Mobitz type II

623	First degree AV block
631	Short PR interval
641	Type-A WPW syndrome
642	Type-B WPW syndrome
643	Atypical WPW syndrome
644	Intermittent WPW syndrome

7 Intraventricular Conductive Defect

Code No.	Description
711	Left bundle branch block
712	Incomplete left bundle branch block
721	Right bundle branch block, plus possible RVH
722	Right bundle branch block
723	Incomplete right bundle branch block
724	RSR in lead V1/V2, consistent with right ventricular conduction delay
731	Left anterior fascicular block
741	Nonspecific intraventricular conduction block

1 Myocardial Infarction

Code No.	Description
1113	Cannot rule out anterior myocardial infarction, probably old
1114	Cannot rule out anterior myocardial infarction, age undetermined
1121	Possible anterior myocardial infarction, possible acute
1122	Possible anterior myocardial infarction, probably recent

1123	Possible anterior myocardial infarction, probably old
1124	Possible anterior myocardial infarction, age undetermined
1131	Anterior myocardial infarction, possible acute
1132	Anterior myocardial infarction, probably recent
1133	Anterior myocardial infarction, probably old
1134	Anterior myocardial infarction, age undetermined
1213	Cannot rule out anteroseptal myocardial infarction, probably old
1214	Cannot rule out anteroseptal myocardial infarction, age undetermined
1221	Possible anteroseptal myocardial infarction, possible acute
1222	Possible anteroseptal myocardial infarction, probably recent
1223	Possible anteroseptal myocardial infarction, probably old
1224	Possible anteroseptal myocardial infarction, age undetermined
1231	Anteroseptal myocardial infarction, possible acute
1232	Anteroseptal myocardial infarction, probably recent
1233	Anteroseptal myocardial infarction, probably old
1234	Anteroseptal myocardial infarction, age undetermined
1313	Cannot rule out anterolateral myocardial infarction, probably old
1314	Cannot rule out anterolateral myocardial infarction, age undetermined
1321	Possible anterolateral myocardial infarction, possible acute
1322	Possible anterolateral myocardial infarction, probably recent
1323	Possible anterolateral myocardial infarction, probably old
1324	Possible anterolateral myocardial infarction, age undetermined
1331	Anterolateral myocardial infarction, possible acute
1332	Anterolateral myocardial infarction, probably recent
1333	Anterolateral myocardial infarction, probably old
1334	Anterolateral myocardial infarction, age undetermined
1413	Cannot rule out septal myocardial infarction, probably old

1414	Cannot rule out septal myocardial infarction, age undetermined
1421	Possible septal myocardial infarction, possible acute
1422	Possible septal myocardial infarction, probably recent
1423	Possible septal myocardial infarction, probably old
1424	Possible septal myocardial infarction, age undetermined
1431	Septal myocardial infarction, possible acute
1432	Septal myocardial infarction, probably recent
1433	Septal myocardial infarction, probably old
1434	Septal myocardial infarction, age undetermined
1513	Cannot rule out lateral myocardial infarction, probably old
1514	Cannot rule out lateral myocardial infarction, age undetermined
1521	Possible lateral myocardial infarction, possible acute
1522	Possible lateral myocardial infarction, probably recent
1523	Possible lateral myocardial infarction, probably old
1524	Possible lateral myocardial infarction, age undetermined
1531	Lateral myocardial infarction, possible acute
1532	Lateral myocardial infarction, probably recent
1533	Lateral myocardial infarction, probably old
1534	Lateral myocardial infarction, age undetermined
1613	Cannot rule out inferior myocardial infarction, probably old
1614	Cannot rule out inferior myocardial infarction, age undetermined
1621	Possible inferior myocardial infarction, possible acute
1622	Possible inferior myocardial infarction, probably recent
1623	Possible inferior myocardial infarction, probably old
1624	Possible inferior myocardial infarction, age undetermined
1631	Inferior myocardial infarction, possible acute
1632	Inferior myocardial infarction, probably recent

1633	Inferior myocardial infarction, probably old
1634	Inferior myocardial infarction, age undetermined
16132	Cannot rule out inferior myocardial infarction with posterior extension, probably old
16142	Cannot rule out inferior myocardial infarction with posterior extension, age undetermined
16212	Possible inferior myocardial infarction with posterior extension, possible acute
16222	Possible inferior myocardial infarction with posterior extension, probably recent
16232	Possible inferior myocardial infarction with posterior extension, probably old
16242	Possible inferior myocardial infarction with posterior extension, age Undetermined
16312	Inferior myocardial infarction with posterior extension, possible acute
16322	Inferior myocardial infarction with posterior extension, probably recent
16332	Inferior myocardial infarction with posterior extension, probably old
16342	Inferior myocardial infarction with posterior extension, age undetermined
171	Abnormal Q wave ? [Lat.]
172	Abnormal Q wave ? [Inf.]
173	Abnormal Q wave ? [Lat., Inf.]
174	Abnormal Q wave ? [Ant.]
175	Abnormal Q wave ? [Ant., Lat.]
176	Abnormal Q wave ? [Ant., Inf.]
177	Abnormal Q wave ?

3 Ventricular Hypertrophy and Atrial Enlargement

Code No.	**Description**
311	Possible right ventricular hypertrophy

312	Right ventricular hypertrophy
313	Right ventricular hypertrophy, probably repolarization abnormality
321	Minimal voltage criteria for LVH
322	Possible left ventricular hypertrophy
323	Moderate voltage criteria for LVH
324	Voltage criteria for LVH
325	Left ventricular hypertrophy, probably repolarization abnormality
331	Possible left atrial enlargement
332	Left atrial enlargement
341	Possible right atrial enlargement
342	Right atrial enlargement

5 ST-T Abnormality

Code No.	**Description**
51	ST abnormality, possible subendocardial ischemia
52	T wave abnormality, possible subendocardial ischemia
53	Nonspecific T wave abnormality
54	ST depression
55	Nonspecific ST elevation
561	Possible acute pericarditis
562	Acute pericarditis
571	ST elevation, possible acute myocardial infarction
572	Tall T wave, possible hyperkalemia

2 Axis Deviation

Code No.	Description
21	Moderate left axis deviation
22	Abnormal left axis deviation
23	S1-S2-S3 pattern
24	Abnormal right axis deviation
25	Right axis deviation
26	Indeterminate axis

9 Others

Code No.	Description
911	Low voltage
912	Low voltage in limb leads
913	Low voltage in chest leads
941	Long QT interval
942	Short QT interval
971	Dextrocardia ?
972	LIMB LEADS REVERSED
973	Abnormal QRS-T angle
974	Consistent with pulmonary disease

981	Artifacts present
982	Cannot be analyzed, re-record recommended

10 Overall Judgment

Code No.	Description
1001	Abnormal ECG
1002	Abnormal rhythm ECG
1003	Borderline ECG
1004	Atypical ECG
1010	Normal ECG

Note: The output codes may be subject to changes without notice.